PREVALENCE AND RISK FACTORS

FOR OSTEOPOROSIS IN ELDERLY MEN

IN A RURAL AREA OF SOUTH INDIA:

A CROSS SECTIONAL STUDY

DISSERTATION SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT OF THE TAMIL NADU DR.M.G.R.MEDICAL UNIVERSITY, CHENNAI, FOR THE DEGREE OF MD BRANCH-XV (COMMUNITY MEDICINE) EXAMINATION TO BE HELD IN APRIL 2016

DECLARATION

I hereby declare that this dissertation titled

"Prevalence and risk factors for osteoporosis among elderly men in a rural area of South India: a cross sectional study" is a bona fide record of my original research. It has not been submitted to any other university or institution for the award of any Degree or Diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

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CERTIFICATE

This is to certify that "Prevalence and risk factors of osteoporosis in elderly men in a rural area of South India:

a cross sectional study" is a bona fide work of

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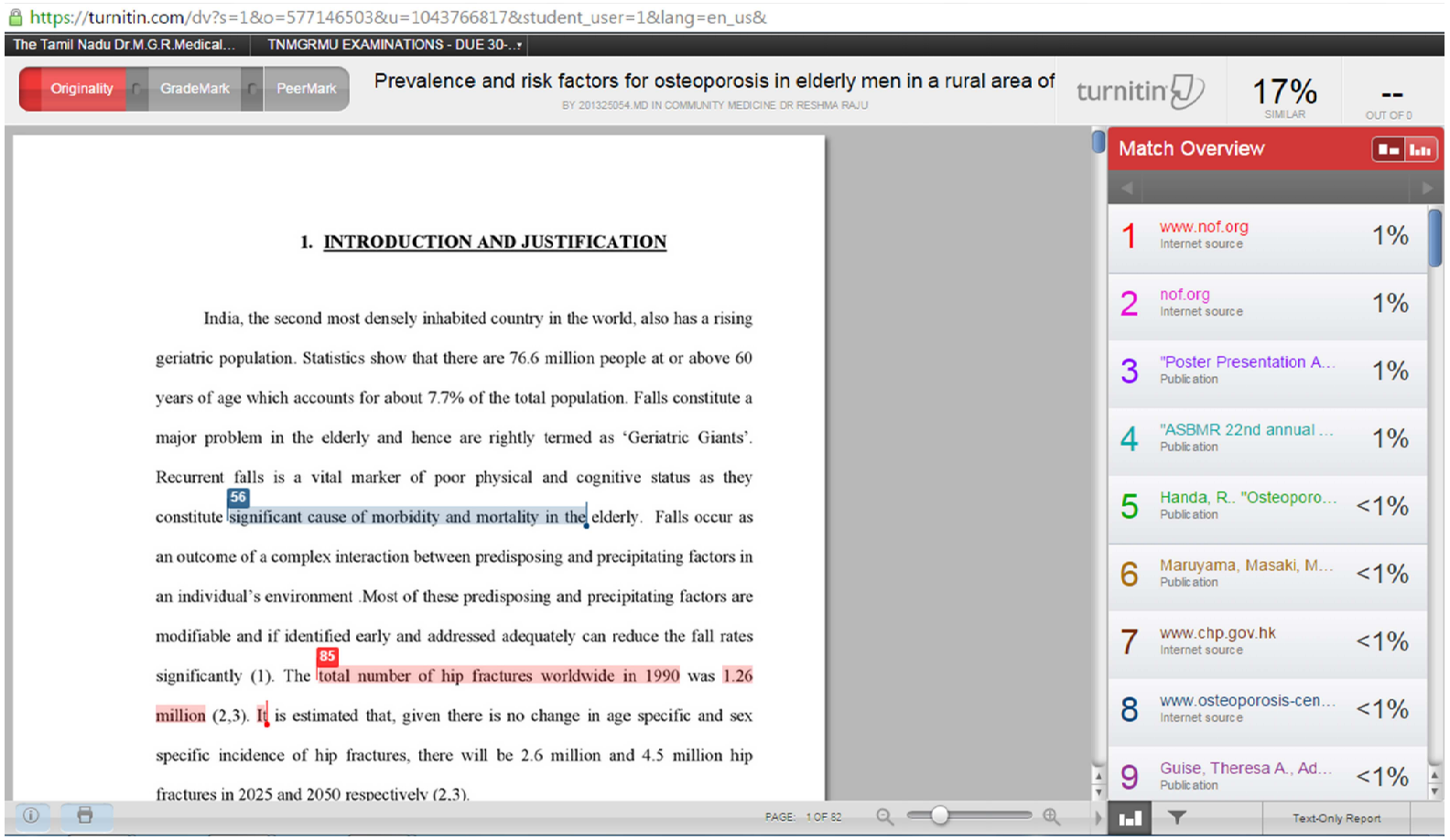

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ACRONYMS

BMD-Bone Mineral Density

BMI-Body Mass Index

BUS-Broadband Ultrasound

CI-Confidence Interval

COPD-Chronic Obstructive Pulmonary Disease

CHAD-Community Health and Development Hospital

CMC-Christian Medical College

DALY-Disability Adjusted Life Years

DEXA-Dual Energy X-ray Absorptiometry

FDA- Food and Drug Administration

FRAX-Fracture Risk Assessment Tool

HA-Health Aid

HEPA-Health Enhancing Physical Activity

ICMR-Indian Council of Medical Research

IOF- International Osteoporosis Foundation

IPAQ- International Physical Activity Questionnaire

ISCD-International Society for Clinical Densitometry

IU-International Unit

MET-Metabolic Equivalent of Task

NIH-National Institute of Health

OR-Odds Ratio

pDXA-Peripheral dual-energy x-ray absorptiometry

PHN-Public Health Nurse

PI-Principal Investigator

PTH-Para Thyroid Hormone

PTCHW-Part Time Community Health Worker

QALY-Quality Adjusted Life Years

QCT-Quantitative computed tomography

QUS-Quantitative ultrasound densitiometry

RDA-Recommended Dietary Allowance

SD-Standard Deviation

SES-Socioeconomic status

25(OH) Vitamin D- 25 Hydroxy Vitamin D

SOS-Speed of Sound

SHBG-Sex Hormone Binding Globulin

UK-United Kingdom

US-United States

USD-United States Dollar

VAT-Visceral Adipose Tissue

WHO-World Health Organization

INDEX OF TABLES

INDEX OF FIGURES

TABLE OF CONTENTS

ABSTRACT

Title of the abstract: Prevalence and risk factors for osteoporosis in elderly men in a rural area of South India: a cross sectional study

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Objective: To determine the prevalence and risk factors of osteoporosis among ambulatory elderly men in the age group of 65 to 80 years in Kaniyambadi block

Methodology: It was a cross sectional study design. Ambulatory elderly men (n=180) in the age group of 65-80 years were selected by simple random sampling from Kaniyambadi block. Sociodemographic details, physical activity, 10 year fracture risk assessment, 24 hour dietary calcium intake, biochemical parameters like calcium, albumin, creatinine and phosphate and Bone Mineral Density were assessed in all the patients.

Results: The prevalence of osteoporosis and osteopenia at any one site in the community was 34.4% (95%CI: 27.31% to 41.48%) and 48.9 % (95%CI: 41.45% to 56.35%) respectively. On multiple logistic regression it was found that BMI (OR:8.3;95% CI: 3.354-20.98 ; p value <0.001), serum albumin (OR: 2.56 ; 95%CI: 1.253-5.267 ;p value:0.010) and education (OR: a 2.43 ;95% CI: 1.050-5.628; p value: 0.038) of the subject had a significant association with osteoporosis.

Conclusion: One out of three elderly men is osteoporotic in Kaniyambadi block. Low BMI, low serum albumin and lack of education are significantly associated with osteoporosis.

Key Words: Osteoporosis, elderly men, serum calcium, serum albumin, physical activity

1. INTRODUCTION AND JUSTIFICATION

India, the second most densely inhabited country in the world, also has a rising geriatric population. Statistics show that there are 76.6 million people at or above 60 years of age which accounts for about 7.7% of the total population. Falls constitute a major problem in the elderly and hence are rightly termed as 'Geriatric Giants'. Recurrent falls is a vital marker of poor physical and cognitive status as they constitute significant cause of morbidity and mortality in the elderly. Falls occur as an outcome of a complex interaction between predisposing and precipitating factors in an individual's environment .Most of these predisposing and precipitating factors are modifiable and if identified early and addressed adequately can reduce the fall rates significantly (1). The total number of hip fractures worldwide in 1990 was 1.26 million (2,3). It is estimated that, given there is no change in age specific and sex specific incidence of hip fractures, there will be 2.6 million and 4.5 million hip fractures in 2025 and 2050 respectively (2,3).

The economic impact of osteoporosis is huge. According to International Osteoporosis Foundation data, in Europe, apart from lung cancer, the disability owing to osteoporosis is much greater than that contributed by cancers. The cost burden of this disease worldwide is expected to increase to USD (United States Dollar) 131.5 billion by the year 2050 (4).

Studies have shown that morbidity and mortality are much higher in osteoporotic men when compared with women (5). In developing countries like India, where men may be the only earning member in the family, such a health condition may push poor families into a vicious cycle of poverty debt and ill health (5).

There is paucity of data on male osteoporosis, an important factor which contributes to fractures in elderly, and thus warrants further research. In order to effectively target osteoporosis and implement programmes, policy makers require precise projections of the burden of the disease (6).

This study is aimed to assess the prevalence of osteoporosis in elderly men in South India so that preventive strategies can be initiated early and hence decrease the disease burden in the community.

2. OBJECTIVES

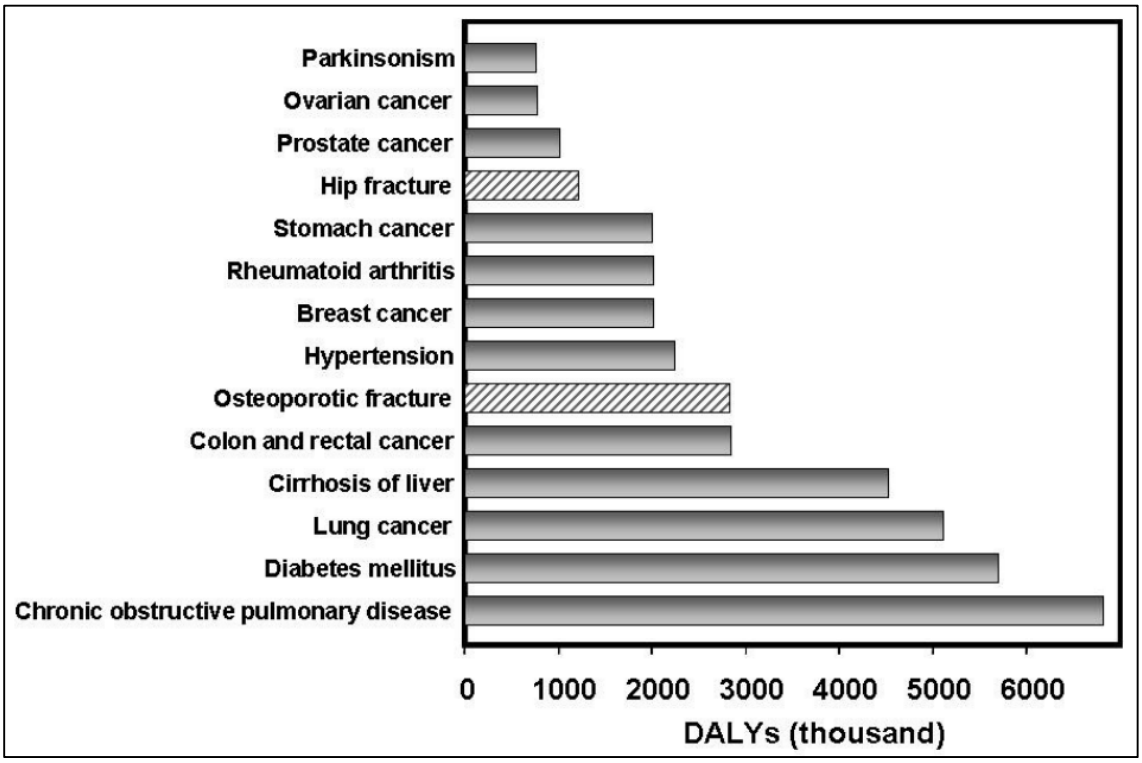
- To determine the prevalence of osteoporosis among ambulatory elderly men in the age group of 65 to 80 years in Kaniyambadi block

- To determine the risk factors for osteoporosis in the same population

3. REVIEW OF LITERATURE

Osteoporosis according to WHO (World Health Organization), is a “disease characterized by low bone mass and micro architectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk” (1). The National Institute of health (NIH) Consensus Development Panel on Osteoporosis defines osteoporosis as “a skeletal disorder characterized by compromised bone strength predisposing a person to an increased risk of fracture” (7). Most people regard osteoporosis as a disease of women. Osteoporosis is rightly called “the silent disease” as it advances devoid of symptoms until fracture occurs (8). The commonest places where fractures occur are vertebrae, hip and wrist. ‘Fragility fractures’ is the terminology used to describe fractures which result as a consequence of secondary osteoporosis (8). Osteoporotic fractures result~~s~~ in significant morbidity, disability and inferior quality of life in the elderly. The past 30 years have witnessed a two to three fold increase in hip fracture rates throughout Asia (9). Hip fractures also can lead to early death and cause a substantial fiscal burden on the family and society (10). Figure 3.1 represents the burden of diseases depicted in DALYs (Disability Adjusted Life Years) for Europe and the United States.

Figure 3.1 Disease burden represented as disability-adjusted life years (DALYs) for USA and European countries together [2002 data] (11)



[Source: "WHO Scientific Group On The Assessment Of Osteoporosis At Primary Health Care Level; Summary Meeting Report ;Brussels, Belgium, 5-7 May 2004"]

Lately osteoporosis in men has been recognized as a significant public health problem as the life expectancy is increasing and the number of elderly men will continue to rise (5,8).

3.1 Prevalence of osteoporosis

International osteoporosis Foundation states that "worlds annual number of hip fracture will rise from 1.26 million cases in the year 1990 to 2.6 million by the year 2025 and to 4.5 million by 2050" (12). Reliable epidemiological data are lacking from India. Data suggests that men are probably affected more than women. This also could be due to the fact that men are likely to seek medical attention than women in

India. In a study done in the Christian Medical College, Vellore in subjects above 50 years of age between 2009 and 2011, osteoporosis of the spine and hip were diagnosed in 42.7% and 11.4% subjects by Hologic DXA-4500 series database (13). However in the same study, on using the ICMR (Indian Council of Medical Research) database, the prevalence was markedly low, was reported to be 27.7% and 8.3% in the spine and hip respectively (13). In men aged above 60 years, the prevalence of osteoporosis was 45% (5). Table 3.1 and Table 3.2 represent the burden of osteoporotic fracture worldwide.

Table 3.1 Prevalence of osteoporosis among elderly men and women (4,14–16).

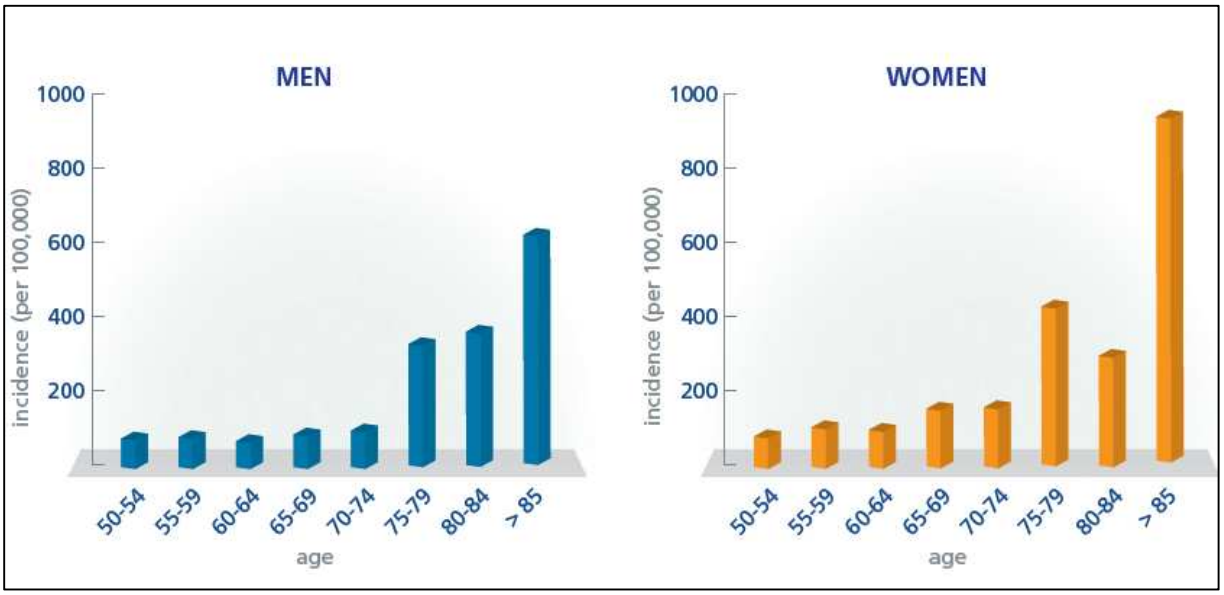
Population		**Prevalence of fracture due to osteoporosis Worldwide**
Women	> 50 years	33%
	> 60 years	50%
Men	> 50 years	20%
	> 60 years	33%

Table 3.2 Site specific and total number of osteoporotic fractures , in men and women more than or equal to 50 years , in various WHO regions (11)

	Expected number of fractures by site(thousands)				All osteoporotic fractures	
WHO region	**Hip**	**Spine**	**Proximal humerus**	**Forearm**	**Number**	**Percent**
Africa	8	12	6	16	75	0.8
Americas	311	214	111	248	1406	15.7
South East Asia	221	253	121	306	1662	17.4
Europe	620	490	250	574	3119	34.8
Eastern Mediterranean	35	43	21	52	261	2.9
Western pacific	432	405	197	464	2536	28.6
Total	1672	1416	706	1660	8959	100

[Source: "WHO Scientific Group On The Assessment Of Osteoporosis At Primary Health Care Level; Summary Meeting Report ;Brussels, Belgium, 5-7 May 2004"]

Figure 3.2 Hip fracture incidence of Rohtak (17)



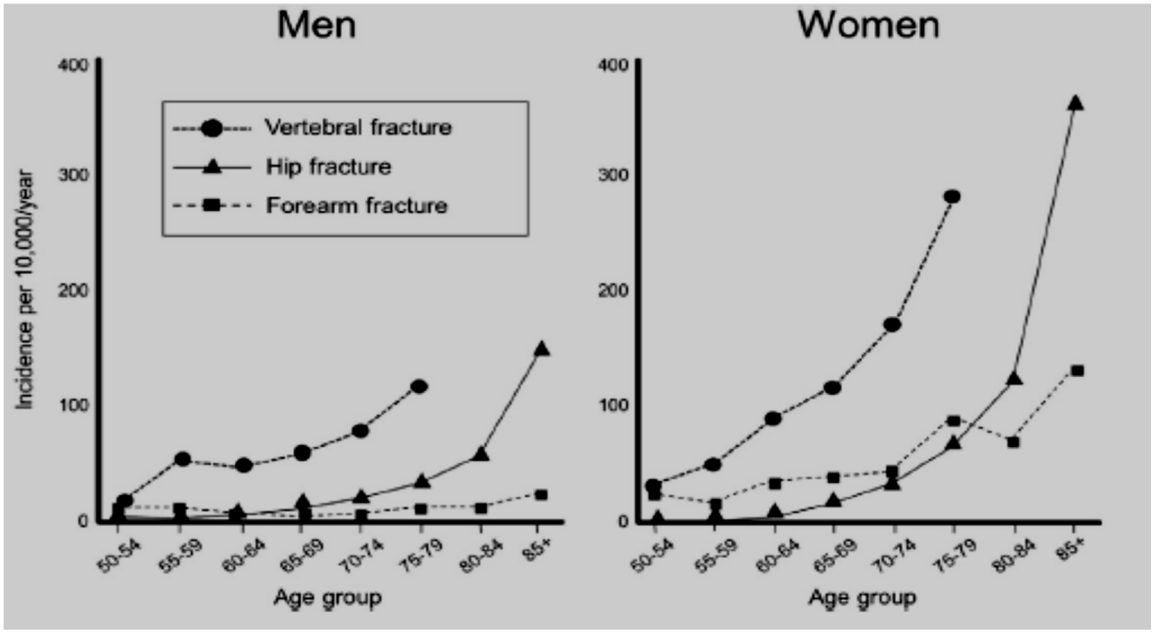
[Source: " International Osteoporosis Federation. The Asia Pacific Regional audit: Epidemology, costs and burden of osteoporosis in 2013".]

Figure 3.2 represents the age and sex specific incidence of hip fracture in the year 2009 in Rohtak district, North India .The incidence of hip fracture starts rising after 65 years of age in both men and women.

3.2. Difference between osteoporosis in men and post menopausal osteoporosis

The lifetime fracture risk for men is between 13 to 25 percent unlike women in whom it much higher reaching to 50 percent. Vertebral fracture prevalence increases both in men and women however the gradient is much steeper in women as is depicted in the Figure 3.3 (18). However fracture related morbidity and mortality is significantly elevated in males than in females (19).

Figure 3.3 "Age-specific and sex-specific radiographic vertebral, hip, and distal forearm fracture incidence" (20)

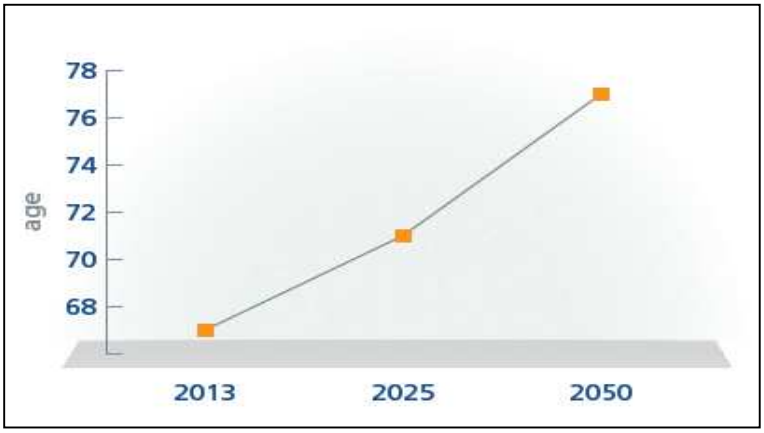


[Source: European Prospective Osteoporosis Study (21) and General Practice Research Database (22)]

3.3 Osteoporosis and an ageing population

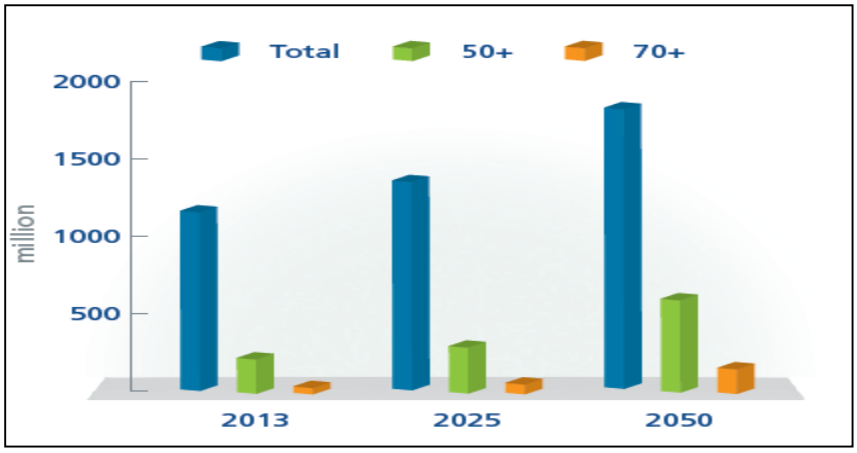
The current population in India is 1.2 billion (17). Ten percent of this population is aged more than 50 years old (17). The current average life expectancy of an Indian is 67 years. The projected population for the year 2050 will be 1.88 billion, of which 33% will be more than 50 years of age. The life expectancy of and average Indian in the year 2050 will be 77 years (17). These statistics point towards an ageing population subsequently resulting in a rise in the number of elderly falls (23). Figure 3.4 and Figure 3.5 represent the life expectancy and the population projection of India respectively. It is estimated that worlds number of hip fracture per year will go up from "1.26 million cases in the year 1990 to 2.6 million by the year 2025 and to 4.5 million by the year 2050" (17).Majority of these fractures can be attributed to osteoporosis (17).

Figure 3.4 Life expectancy in India (17)



[Source: "International Osteoporosis Federation. The Asia Pacific Regional audit: Epidemology, costs and burden of osteoporosis in 2013"]

Figure 3.5 Population projection for India until 2050 (17)



[Source: "International Osteoporosis Federation. The Asia Pacific Regional audit: Epidemology, costs and burden of osteoporosis in 2013"]

3.3.1 Medical Impact of osteoporosis

The most important clinical sequel of osteoporosis is a fractureand its associated consequences. The common sites of fractures due to osteoporosis are spine, proximal femur and distal forearm. The outcome of fractures can either be full improvement or pain, disability and even fatality. As a result of the fracture patients may experience psychological symptoms like low self esteem and depression due to the tenderness, disability and lifestyle modification. The high morbidity and subsequent dependency as a result of the fracture can damage interpersonal relationships and social interactions of the patient and their care givers (24).

There is a 2.5 times increased risk for future fractures in people with hip fracture and they can have 10-20% excess mortality within the first year. Around 20%

of these patients require prolonged stay in a nursing home. Pre-fracture level of independence is regained only by 40% of these patient (24–26).Wrist fractures may be less disabling but can result in restrictions of activities of daily living. Mortality is also high with vertebral fractures and it also causes people to have long term pain and disability (24).

3.3.2 Economic toll

A report from the Surgeon General (US) 2004 estimates that there are 432,000 admissions to the hospitals, almost 2.5 million consults with the medical officers and about 180,000 admissions in various nursing homes per year in the US as a consequence of osteoporotic fractures (25). The cost to the health care delivery system is also high which is estimated to be at least $17 billion in the year 2005 (6). In the US the number and related costs of fractured hip could become two or three times by 2040 due to the aging population. In India the cost of treatment of fracture varies depending on the place and type of health facility as in whether it is private clinic or government hospital. The cost of hip surgery in a private hospital is about Rs 1,50,000 to 2,50,000/- (2,360-3,860 USD) and the duration of stay will be approximately 5-6 days. In a government hospital the cost will be only 50,000/- but the duration of stay will be 15 days (27).

3.4 Risk factors associated with falls in the elderly

Among the several causes of falls in the elderly, accidental or environment related is the most common, accounting for 30-50% of the cases. Next in the list is

gait problems and weakness contributing for 10-25% cases. Gait abnormalities can be either due to simple age related changes or specific dysfunctions involving nervous, muscular or skeletal systems. Another major factor which contributes to fall among elderly is dizziness which is very common in this age group. Several factors such as cardiovascular dysfunction, orthostatic hypotension, drug side effects may be responsible for this. About 2-10% of the falls can be attributed to syncopal attacks or sudden loss of consciousness. Other specific causes include neurovascular diseases, poor cognition, visual disturbances, adverse effects of drugs, anemia, alcoholism, severe osteoporosis with spontaneous fracture (28). [See Table 3.3]

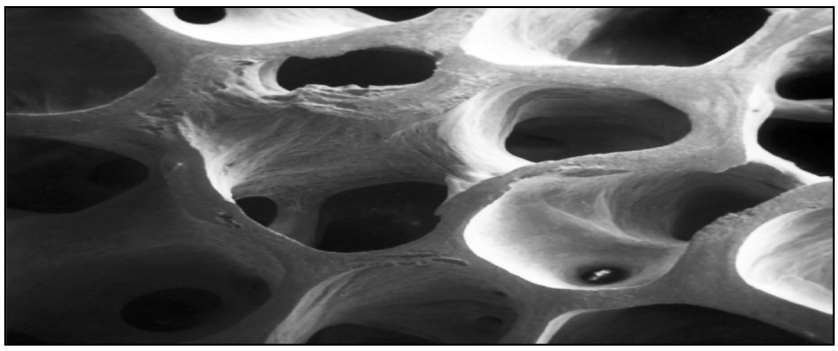
Table 3.3 Risk factors for fall

Medical factors	Neuromuscular factors	Environmental factors
• Elderly age group • Cardiac arrhythmias • Pscychiatric ailments • Malnutrition • Reduced mental acuity • Dehydration • Orhtostatic hypotension • Vitamin D deficiency • Sedative drugs	• Muscle weakness • Lack of proprioception • Poor balance • Kyphoscoliosis	• No assistive devices in the bathroom for the elderly • Slippery floor • Poor lighting • obstacles in the path

3.5 Basic pathophysiology

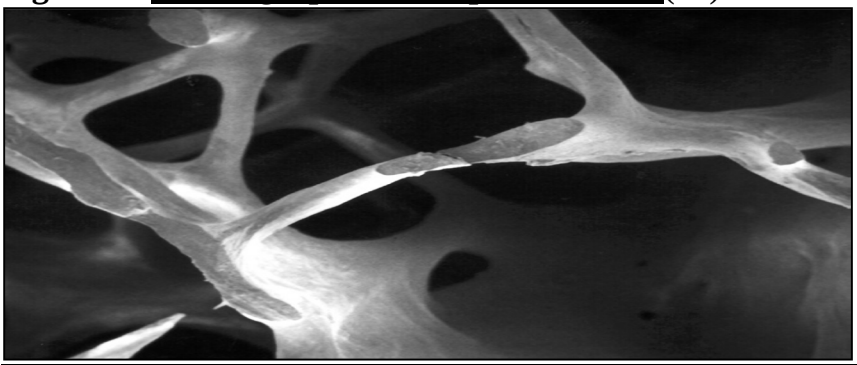
Peak bone mass is attained by the age of 18-25 years and it is dependent on various factors such as genetics, diet, endocrine disorders, exercise and health during growth. Because of bone remodeling the older bone is continuously replaced by newer bone. When this equilibrium is lost as in menopause and advancing age, where by bone removal is more than replacement it results in bone loss (24). Figure 3.4 and Figure 3.5 represents the micrograph of a normal and osteoporotic bone respectively (29).

Figure 3.6 Micrograph of normal bone (24)



[Source: "Clinicians guide to prevention and treatment of osteoporosis. National Osteoporosis Foundation"]

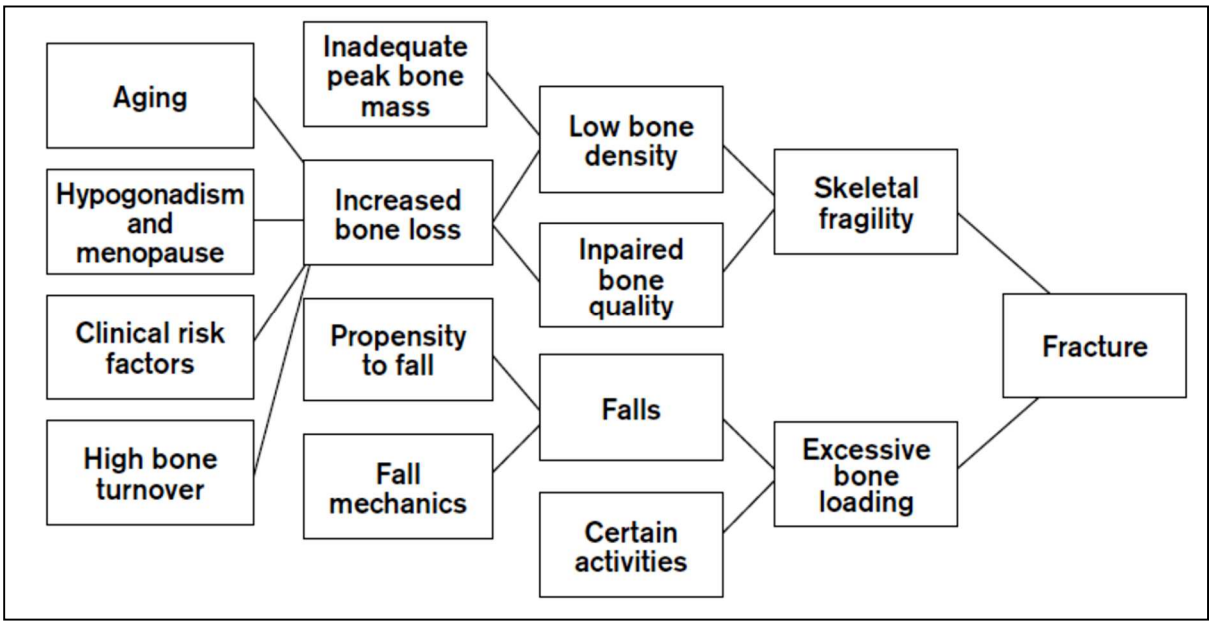
Figure 3.7 Micrograph of osteoporotic bone (24)



[Source: "Clinicians guide to prevention and treatment of osteoporosis. National Osteoporosis Foundation"]

As a result of bone loss there will be disordered skeletal architecture and changes in the cancellous bone which can lead to fractures. There is loss of trabecular plates of bone resulting in structurally frail skeleton which increases bone fragility and fracture risks.

Figure 3.8 Pathogenesis of osteoporosis related fractures (30)



[Source: "Clinicians guide to prevention and treatment of osteoporosis. National Osteoporosis Foundation"]

Figure 3.8 represents the various general and specific causes of osteoporotic fractures. Ageing, hypogonadism, menopause, other medical risk factors and increased bone turnover lead to increased bone loss. This along with inadequate peak bone mass leads to impaired bone quality and low bone density. In addition to this various factors such as increased propensity to fall and fall mechanics will result in

skeletal bone fragility and increased bone loading which finally culminate in fracture bone (30).

3.6 Bone loss linked with aging in men

When compared to females, males have larger bones, have greater bone strength and reduced risk of fractures. From middle age, the bone loss in men starts progressing. Men in contrast to women have a lower resorption of the endocortex and a greater expansion of periostium. The periosteal apposition may work against the cortical thinning produced by endocortical resorption. This result in lower total bone loss compared to women which ultimately leads to an absolute increase in the size of the bone. Reduced bone formation leads to trabecular thinning resulting in bone loss in elderly men (31). The role of estrogen, androgen and Sex Hormone Binding Globulin (SHBG), in the pathogenesis of osteoporosis in men, needs to be clarified. The most dreaded complication of bone loss is hip fracture which is more in men in comparison to women (5).

3.7 Causes and risk factors of osteoporosis in men

Several factors contribute to osteoporosis and subsequent fractures in men. It can be classified as “modifiable” and “non-modifiable” risk factors. Non-modifiable risk factors include gender, age, ethnicity, family history, body frame. Some of the modifiable risk factors include lack of physical activity, low dietary calcium intake, low vitamin D levels due to lack of sunlight exposure, eating disorders, excessive

alcohol intake, smoking. Bariatric surgeries and post-gastrectomy status can also cause osteoporosis due to the reduced surface area available for the absorption of nutrients. Another important factor is use of medications such as steroid, anticonvulsant and chemotherapeutics .Endocrine disorders such as hyperthyroidism, hyperparathyroidism, and hypogonadism are some of the other identified risk factors (12,17–19,21).

Some chronic diseases such as coeliac disease, inflammatory bowel disease, rheumatoid arthritis, chronic liver or kidney disease also contribute to this condition (32–34).Studies done in COPD (Chronic Obstructive Pulmonary Disease) patients to determine the prevalence of osteoporosis among them revealed a higher prevalence of osteoporosis. Glucocorticoid use alone could not explain the increased prevalence of osteoporosis in them (35).

Reduced physical activity is a key risk factor for osteoporosis. Studies show that weight bearing physical activity during formative years contributes to increased peak bone mass. This will give the mechanical stimuli or ‘loading’ which is essential for the preservation of bone health. It also reduces the rate of bone loss later in life (36).When the physical activity is increased, the risk of fractures in the future is less (37).

Table 3.4 describes the causes of osteoporosis in men classified into primary and secondary causes. The causes of primary osteoporosis are age related and idiopathic. Secondary osteoporosis occurs as result of certain medical conditions or

drugs which interfere with bone remodeling and lead to increased bone loss. Factors such as renal failure, cushing's disease, liver impairment , alcoholism, steroid use, hypogonadism, drug induced, COPD are the main causes for secondary osteoporosis in men (31).

Table 3.4 Primary and secondary osteoporosis in men (24,31)

Primary Osteoporosis	
• Osteoporosis associated with ageing	• Idiopathic
Secondary Osteoporosis	
• **Alcohol addiction** • **Glucocorticoid use** ✓ Exogenous ✓ Endogenous • **Hypogonadism** ✓ Idiopathic ✓ Androgen deprivation therapy for prostate cancer • **Chronic obstructive pulmonary disease** • **Gastrointestinal diseases** ✓ Malabsorption syndromes ✓ Celiac sprue ✓ Primary biliary cirrhosis ✓ Inflammatory bowel disease ✓ Bariatric surgery ✓ Postgastrectomy	• **Hypercalciuria** • **Hyperthyroidism** • **Hyperparathyroidism** • **Medication related** ✓ Anticonvulsants ✓ Chemotherapeutics ✓ anti coagulants (heparin) ✓ aromatase inhibitors ✓ gucocorticoids(≥5mg/d of prednisolone or equivalent for 3 months) ✓ Lithium • **Thyroid hormone** • **Neuromuscular disorders** • **Post-transplant osteoporosis** • **Systemic illnesses** ✓ Mastocytosis ✓ Thalassemia-induced osteoporosis ✓ Monoclonal gammopathy ✓ Other malignancies ✓ Human immunodeficiency virus (HIV) infection ✓ Rheumatoid arthritis

3.8 Evaluation of osteoporosis in men

Assessment of BMD (Bone Mineral Density) is essential to establish the diagnosis of osteoporosis which is the gold standard (38). It is proven that the strongest risk factor for fracture is a low BMD. For people who are at risk, a clinical diagnosis can easily be made in case of a low trauma fracture.

3.8.1 Indications for DEXA scan (24)

According to the National Osteoporosis Foundation (NOF), the decision to screen for osteoporosis depends on each person's fracture risk profile and bone health estimation (24). Bone Mineral Density measurement is not recommended unless the result will affect his or her treatment decision. It is not advised in children, adolescents, young men or premenopausal women. Table 3.5 lists the indication for BMD testing according to NOF guidelines.

Table 3.5. Indications for BMD testing (24)

- Adults above 50 years with a fracture
- Adults with a medical condition like rheumatoid arthritis or on treatment with steroids and with reduced bone mass
- Subjects requiring treatment for osteoporosis
- To monitor treatment effect of patients on treatment for osteoporosis
- people currently not on therapy in whom evidence of bone loss would initiate treatment

3.8.2 Definition of osteoporosis based on BMD

Screening for osteoporosis in men is recommended above 70 years of age (5). Bone mineral density measured by a DEXA (Dual Energy X ray absorptiometry) is the gold standard in diagnosis of osteoporosis. Areal BMD can be expressed both in absolute and relative terms. In absolute terms BMD can be expressed as grams of mineral per square centimeter scanned (g/cm^2) (24). The Z-score represents the areal BMD compared to the BMD of a matched reference population, age, sex and ethinicity being matched. The T-score on the other hand represents the BMD compared to the BMD of a young adult in the reference population of the same sex (24). In order to calculate the T-score and Z-score, divide the difference between the patients BMD and the mean BMD of the reference population by the standard deviation of the reference population (24).

Table 3.6 "WHO definition of Osteoporosis Based on BMD" (24)

Classification	**BMD**	**T-score**
Normal	"Within 1 SD of the mean level for a young-adult reference population"	"T-score at -1.0 and above"
Low Bone Mass (Osteopenia)	"Between 1.0 and 2.5 SD below that of the mean level for a young-adult reference population"	"T-score between -1.0 and -2.5"
Osteoporosis	"2.5 SD or more below that of the mean level for a young-adult reference population"	"T-score at or below -2.5"
Severe or Established Osteoporosis	"2.5 SD or more below that of the mean level for a young-adult reference population"	"T-score at or below -2.5 with one or more fractures"

[Source: "Clinicians guide to prevention and treatment of osteoporosis. National Osteoporosis Foundation"]

Definition of osteoporosis is based on the bone mineral density. According to the WHO criteria for the diagnosis of osteoporosis, it has been defined as a “BMD that lies 2.5 standard deviations or more below the average value for young healthy women (a T-score of <-2.5 SD)” (24). The diagnosis based on BMD, as “normal”, “osteopenia”, “osteoporosis” and “severe and established osteoporosis” is dependent on the WHO diagnostic classification shown in Table 3.6 (24).

BMD of lumbar spine, hip, forearm, heel and fingers can be calculated to predict the site specific and the overall assessment of future fracture risk. However BMD assessment of the hip is the best predictor of potential hip fracture risk in the future. In men above 50 years of age the diagnosis of osteoporosis is based on the WHO diagnostic T-score criteria applied to BMD measurement by central DEXA at the lumbar spine and femoral neck (24). According to the International Society for Clinical Densitometry (ISCD) in men less than 50 years, in the place of T-score, ethnic or race adjusted Z-scores should be considered. In this group of patients with Z-scores of -2.0 or lower is classified as either “low bone mineral density for chronological age” or “below the expected range for age” and those with Z-score of more than -2.0 being “within the expected range for age” (24).

One of the main problem with the measurement of BMD is that it has high specificity but low sensitivity which signify that the fracture risk is more in the presence of low BMD but is not negligible in case of normal BMD. So a greater part

of the osteoporotic fractures occurs in patients with a DEXA scan. Hence experts do not advise the mass screening of BMD.

3.8.3 DEXA Machine:

Dual-energy X-ray absorptiometry (DEXA) scanning was designed for the diagnosis of osteoporosis. It was primarily used to clinically analyze the main sites such as the lumbar spine, femoral neck and forearm. The hasty acceptance of DEXA has led to the development of dissimilar, contending generations of the device. Improvements have been made through introduction of latest technologies in X-ray production and detection, modification of data acquirement protocols, and accomplishment of more complex image analysis algorithms. Thus the use of DEXA has allowed the study of the total skeleton, regional parts, and also the soft-tissue composition measurement. This technology has given the ability to easily measure with greater precision and low scanning time, the body fat mass, lean mass and bone mineral density(39).

A Hologic Dual energy X-Ray absorptiometry (DEXA) machine (Discovery A- QDR 4500) has a one pass single sweep scanning system for better quality and precision. It also eliminates beam overlap errors and image distortion encountered in rectilinear acquisition techniques resulting in a better image quality and data stability. It has a multi-element digital detector array along with true fan-beam acquisition geometry, enabling rapid, dual-energy bone density measurements.

3.8.4 Use of WHO Fracture Risk Algorithm (FRAX)

FRAX is a tool which was designed to calculate the 10 year probability of a hip fracture and the 10 year probability of a major osteoporotic fracture which can be either a vertebral, hip, forearm or proximal humerus fracture using femoral neck BMD and various clinical risk factors. Quite a few risk factors were included in the WHO 10-year fracture risk model. Given below is the Table 3.7 containing those risk factors which are considered to predict the 10 year fracture risk (24).

Table 3.7 Factors included in WHO fracture risk assessment model (24)

Risk factors included in the WHO Fracture Risk Assessment Model	
• Current age • Gender • A prior osteoporotic fracture (including morphometric vertebral fracture) • Femoral neck BMD • Low body mass index (kg/m2) • Oral glucocorticoids ≥5 mg/d of prednisone for ≥3 mo (ever)	• Rheumatoid arthritis • Secondary osteoporosis • Parental history of hip fracture • Current smoking • Alcohol intake (3 or more drinks/d)

Other laboratory tests mentioned in Table 3.8 may be required in order to find out the cause of the disease (31).

Table 3.8 Laboratory tests in the evaluation of male osteoporosis (31)

Other investigations
Serum calcium
Serum phosphorus
Serum creatinine
Alkaline phosphatase
Liver function tests
Complete blood count
Protein electrophoresis
Serum 25-hydroxy-vitamin D
Serum testosterone
Sex hormone binding globulin
Luteinizing hormone
Additional second line tests
Parathyroid hormone, thyroid function
24-h urinary calcium and creatinine
24-h urinary cortisol
Biochemical indices of bone remodeling
Immunological tests for sprue

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3.8.5 Other Bone densitometry Technologies

There are several bone mass measurement technologies which are able to predict site specific and overall fracture risks. These newer technologies are capable of giving accurate and highly reproducible results if performed according to the acceptable standards.

- **Peripheral Dual-Energy X-ray Absorptiometry (pDXA):** This measures the areal bone density of peripheral bones such as forearm, fingers and heels. It can also be used to measure the bone density of vertebrae. Though it can be used to predict the overall fracture risk in women there is not enough evidence regarding fracture prediction in men. It is not useful in monitoring BMD during or after treatment(24).
- **CT based absorptiometry:** Quantitative **computed tomography (QCT)** measures volumetric trabecular and cortical bone density at the spine and hip. Peripheral QCT is used for the forearm or tibia. It can be used to predict fracture risks in women but there are no sufficient data to suggest its usefulness in fracture prediction in men. The radiation exposure associated with this modality is much higher than the DEXA (24).

- **Quantitative ultrasound densitometry (QUS):** It measures the “speed of sound (SOS)” and or “broadband ultrasound attenuation (BUS)” at various bones. It can be used to predict fracture in post menopausal women and men above 65 years of

age. The fact that it is not associated with any radiation exposure is an added advantage (24). Calcaneal QUS still remains the commonest modality of diagnosis of osteoporosis in places where DEXA scan are not available (40).

3.9 Recommendations for all patients

Several strategies can be provided for all patients to reduce fracture risks. These include appropriate amount of calcium and vitamin D in the diet, regular involvement in weight-bearing and muscle-strengthening physical activities, cessation of smoking and alcoholism, and treatment of other risk factors for fracture such as lack of vision, loss of balance, giddiness etc.

- **Dietary Calcium and Vitamin D:** Human skeletal system contains almost 99% of the body's calcium stores. When the dietary intake of calcium is low; there will be bone resorption from the skeleton to preserve the serum calcium at a constant level. Vitamin D plays a major role in the absorption of calcium. According to the NOF, an intake of 800 -1000 IU (International Unit) of vitamin D per day for adults older than 50 years of age is required. The expected level of serum 25 (OH) Vitamin D level is 30 ng/ml (75 nmol/L) or higher. Studies have shown that supplementation of calcium and vitamin D combinations can effectively diminish fracture risks. All individuals are recommended to have a minimum of 1200mg of dietary calcium including supplements. The main dietary sources of vitamin D include milk, cereals, egg yolk, salt water fish and liver. The present recommendation to reduce

sodium, increase potassium and fresh fruit and vegetables is improbable to be harmful for bone health (10). However vegetarian diet alone has not proved any beneficial effect. The presence of high contents of phytates, oxalates and fiber promotes calcium resorption and its secretion in the urine (41).

- **Physical activity:** Regular physical activities reduce the risks of falls and fractures. Health benefit of regular exercise includes improvement in strength, posture and balance. It also improves the bone density. As the benefits of physical activity stops when the person stops exercising it is strongly recommended to persist in exercise at all ages. Weight bearing exercises are those in which both the bone and the muscles work against gravity while the feet and the legs bear the body's weight. Some examples of weight bearing exercise include walking, jogging, dancing, climbing stairs and playing tennis (24).
- **Fall prevention:** Strategies to prevent falls include regular checking and correcting of vision and hearing, evaluating any neurological problems. Alternate medicines can be prescribed for those drugs which may affect balance (24).
- **Avoidance of tobacco use and excessive alcohol intake.** The use of tobacco is disadvantageous to the bone health. Hence elderly men should be encouraged to avoid smoking. Excessive drinking defined as three or more units of alcohol per day is injurious to the bone. It also enhances the chance of falling (24). .

3.10 Treatment of osteoporosis in men

General measures to prevent fractures needs to be adopted in every elderly man as is the case with women. These include good nutrition, adequate calcium intake, regular exercise, avoiding harmful lifestyle factors (*e.g*., smoking cessation). Due to high prevalence of vitamin d deficiency, its supplementation should be considered always in order to achieve adequate blood level (31).

The underlying cause of osteoporosis should always be investigated and treated if possible.

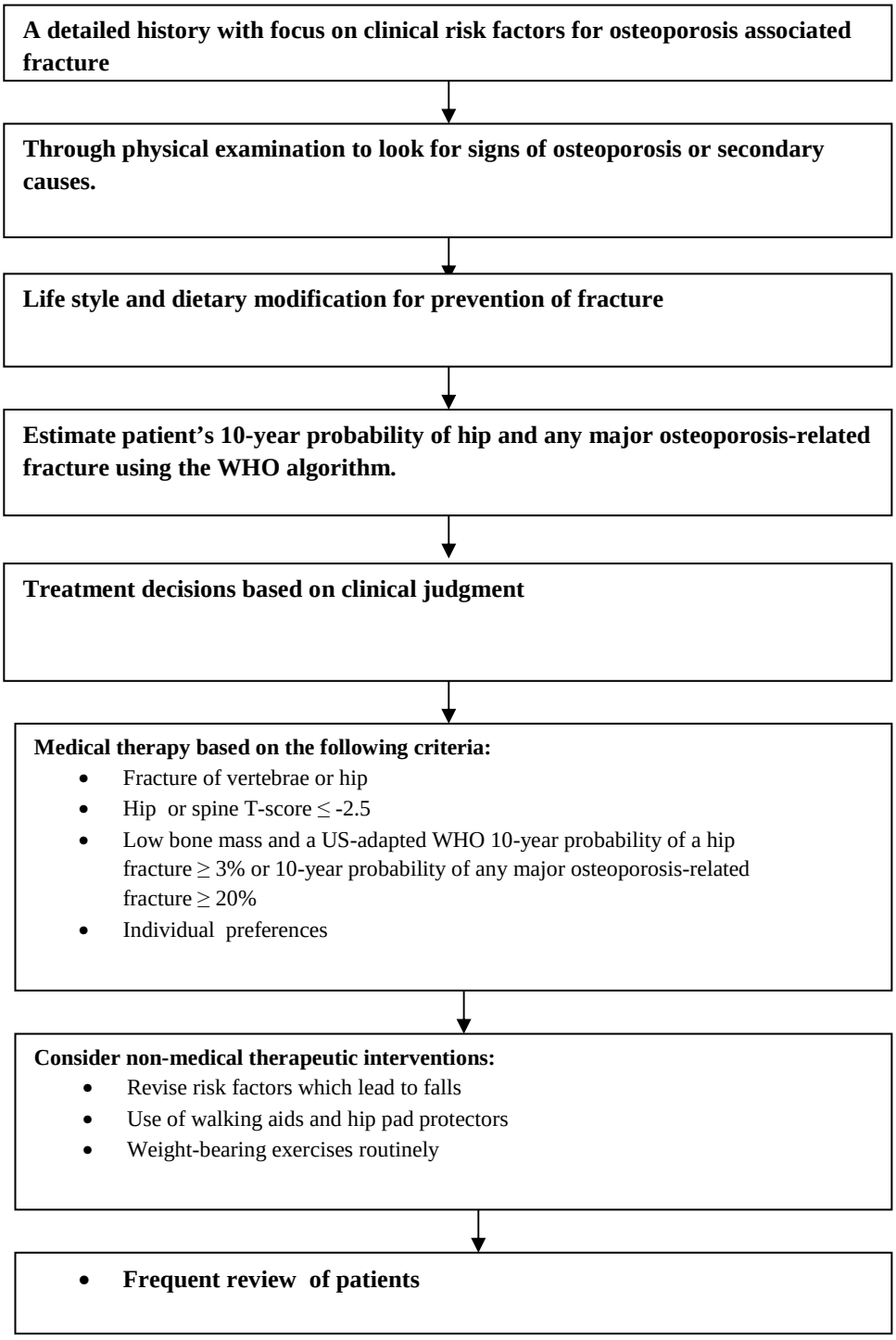
3.10.1 Subjects requiring treatment?

Post menopausal women and elderly men above 50 years in any of the following situation should be offered medical management.

- Any fracture in the hip or spine
- femoral neck or spine T-score $\leq$ -2.5 after excluding secondary causes
- "T-score between -1.0 and -2.5 at the femoral neck or spine along with a 10-year probability of a hip fracture $\geq$ 3% or a 10-year probability of a major osteoporosis-related fracture $\geq$ 20%" (24).

Assessment of the patients with suspected osteoporosis can be done by following the algorithm shown in Figure 3.9.

Figure 3.9 Algorithm for assessment of osteoporosis (24)



Medical therapy available for prevention and treatment of osteoporosis in women are bisphosphonates and calcitonin. Other drugs are estrogens (estrogen and/or hormone therapy), estrogen agonist/antagonist (raloxifene) and parathyroid hormone [PTH (1-34), teriparatide]. Examples of bisphosphantes include alendronate, alendronate plus D, ibandronate, risedronate, risedronate with 500 mg of calcium carbonate and zoledronic acid. everal randomized controlled trials were under taken in men to test various pharmacological agents useful for treatment in men. Most of these were short term trials with small sample size and hence lacks power to make conclusive evidence on the drug effects on fracture risks (31).

Studies show that bisphosphonates, strontium ranelate, teriparatide and denosumab improve bone mineral densities in men with both primary and secondary osteoporosis. The beneficial effects of bisphosphonates and teriparatide on bone mineral density were independent of age and gonadal function. Study done comparing use of bisphonates versus placebo and incidence of new vertebral fractures showed a statistically significant difference between the two (31).The treating physician should weigh the potential risk versus benefit in treating with pharmacological agents in each case.

3.10.2 Bisphosphonates

Bisphonates are anti-resoptive agents. Osteoporosis as well as other metabolic bone diseases such as pagets disease and tumor associated bone diseases are effectively treated with this drug. The strong binding property of bisphosphonates

with the bone prevent osteoclast mediated bone resorption. This results in the anti-resoptive property of bisphosphonates. Bisphonates are the treatment of choice for most men with osteoporosis (42).

3.10.3 Alendronate

Another drug approved in treating men with osteoporosis is Alendronate. It represents a vital and desirable medical advancement in the management of osteoporosis in men (43). Alendronate decreases the 3 year future risk of fractures (spine or hip), by 50% in those with earlier fractures and 48% in those without an earlier fracture. The preventive dose recommended is 5mg once daily or 35mg once weekly. The therapeutic dose is double the preventive dose or 70mg once weekly with Vitamin D3 (2800IU or 5600IU) (24,42). The safety and tolerability of alendronate in men is similar to that observed for post menopausal women (43).The incremental benefit of Alendronate in increasing bone density and thus preventing fractures has been proven in earlier studies. It also prevents decline in height (44). A Swedish study concluded that treating men with osteoporosis was cost effective (45).

3.10.4 Risedronate

Risedronate is also used for management of osteoporosis in men. It increases the bone mass. Incidence of spine fracture reduces by 41-49 percent and other fractures by 36 percent after treatment with risedronate for over three year. Studies show that there is a marked reduction in the risk even with treatment for one year in

patients with previous vertebral fractures. Several dosage regimens are available which include " 5 mg daily tablet; 35 mg weekly tablet; 35 mg weekly tablet along with six tablets of 500 mg calcium carbonate; 75 mg tablets on two consecutive days every month; and 150 mg monthly tablet" (24). A multinational randomized double blinded placebo controlled two year study done to evaluate the efficacy and safety of 35 mg weekly once dose of risedronate in men with osteoporosis, it was seen that there was a significant increase in the lumbar spine BMD from the baseline (4.5%; 95% CI: 3.5%, 5.6%; $p < 0.001$) (46). However there was no drop in incident fractures with the use of risedronate as these arise rarely and this study was not powered to capture improvements in fracture end points (47). Hence more studies are needed to determine the anti-fracture efficacy of risedronate (47).

3.10.5 Zoledronic acid

Zoledronic acid is also an approved drug for treatment of osteoporosis in men. Incidences of spine fractures are reduced by 70 percent with considerable reduction of risk at the end of one year. It also reduces the incidence of hip fracture and non-vertebral fractures by 41 percent and 25 percent respectively. The dose of zoledronic acid is "5 mg by intravenous infusion over at least 15 minutes once year for treatment and once every two years for prevention" (24,42). In a multicenter, double-blind, placebo-controlled trial, 1199 men between 50 to 85 years with primary or hypogonadism-associated osteoporosis were randomly assigned to obtain an intravenous infusion of zoledronic acid (5 mg) or placebo at baseline and at 12

months. The results show that there is a 67% reduction in risk in the group who were given Zoledronic acid (Relative Risk: 0.33; 95% CI: 0.16 to 0.70; P=0.002) (48). The advantages of zoledronic acid are that it does not have gastrointestinal side effects as it administered intravenously. Also it offers less frequent dosing regimens and thus adherence to therapy is more (47).

3.10.6 Side effects of bisphosphonates

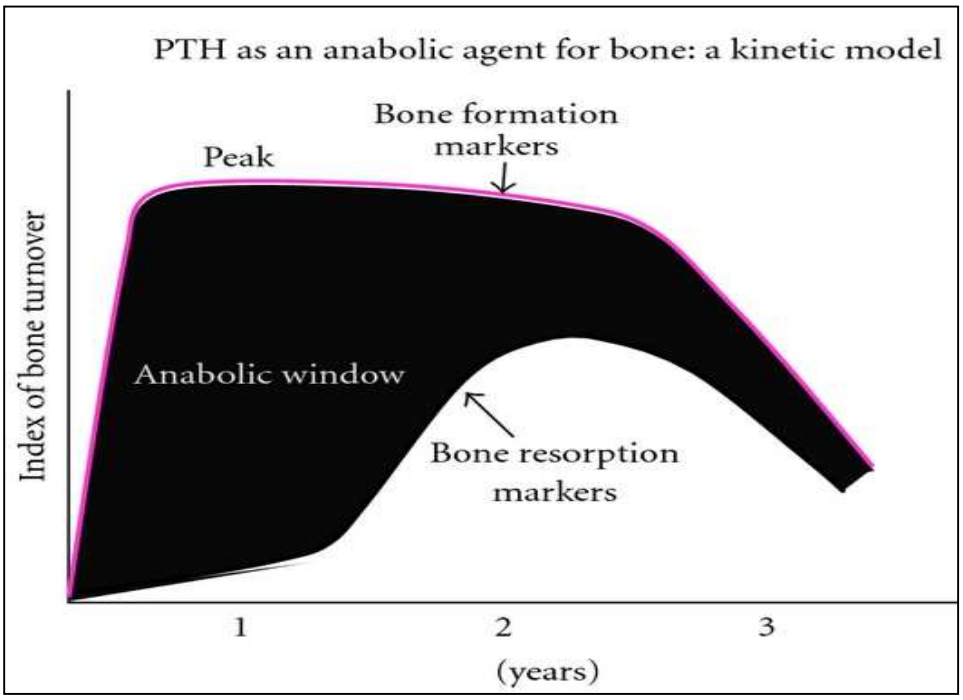
Alendronate and risedronate must be ingested before food. Hence the adverse effects of bisphosphonates include inflammation of the oesophagus and gastric ulcers. Osteonecrosis of jaw is a rare complication of bisphosphonates especially after intravenous administration. Visual disturbances have also been documented which if occurs must be immediately reported to the treating physician. Incidence of atrial fibrillation is also higher among patients treated with zoledronic acid when compared to patients on placebo (24)

3.10.7 Parathyroid hormone

Another FDA (Food and Drug Administration) approved drug for management of osteoporosis in men is Parathyroid hormone. It is a recombinant fragment of human parathyroid hormone (PTH) (49). It is a bone building anabolic agent which is administered as daily subcutaneous injections. Daily dose of 20 micrograms administered for eighteen months can lower the incidence of both vertebral and non-vertebral fractures by 65 percent and 53 percent respectively (49). Studies have shown that PTH is a potent skeletal bone stimulator and is associated with considerable

increase in lumbar spine and hip bone density (49). Teriparatide or PTH (1-84) first stimulates bone formation and then it is followed by an increase in bone resorption which is termed as “The anabolic window” and is shown in Figure 3.12 (50,51).

Figure 3.10 “The anabolic window” (50)



[Source: Bilezikian JP. Combination anabolic and antiresorptive therapy for osteoporosis: opening the anabolic window]

Animal studies have shown an increased incidence of osteosarcoma in rats. The drug has doubtful safety and efficacy beyond two years of treatment (24,42). The contraindications for use of teriparatide are primary hyperparathyroidism, children having open epiphyses, pagets disease of bone and past history of osteosarcoma (51).

3.10.8 Conclusion

Awareness about male osteoporosis is low in developing countries like India and this condition is still under diagnosed and under treated here. Osteoporotic fractures are a major public health problem. There is a paucity of data regarding the risk factors and their influence on bone health in an Indian context (5). Adequate knowledge of the risk factors of this disease in our population will enable us to take right measures in order to adopt preventive measures like avoiding smoking, reduing alcohol intake, and increasing level of physical activity , daily calcium intake , adequate intake of vitamin D at an earlier stage (8). Further research work is warranted in the field of male osteoporosis so that pathogenesis is clarified (42). Studies are also urgently required exploring the treatment options of male osteoporosis.

4. METHODOLOGY

4.1 Health care delivery system in CHAD

Medical care for patients in and around Kaniyambadi block is offered by Community Health Department of CMC Vellore (CHAD hospital). Patients from the block are provided with health care at the peripheral level through a health care delivery system which has health workers at various levels. At the grass root level, the Part Time Community Health Worker (PTCHW), one for every 1000-1500 population, visits patients in their area and report to Health aides (HA) who are in charge of 5000 population and they record in appropriate registers. They are supervised by the Public Health Nurse (PHN), one for every 15,000 population. The PHN visits the village once in two weeks and the HA visits every village once a week. This is complimented by a doctor visiting each area once a month. All patients with chronic diseases like diabetes mellitus and hypertension will be seen in the doctor run clinic and given medications. Any patient requiring investigations or hospital care will be referred to CHAD where the patient will be evaluated and if found to be very sick will be referred to CMC which is our tertiary center located around 8Km from CHAD for advanced medical care.

4.2 Study design

This study is a cross sectional study done among the elderly men between 65 years and 80 years in Kaniyambadi block to find out the prevalence and risk factors for osteoporosis.

4.3 Study setting

The study was done in Kaniyambadi block. Thirteen villages were chosen by simple random sampling. Elderly men between the age group of 65 to 80 years were eligible for the study. Around fifteen to twenty patients were selected from each village by simple random sampling. Patient recruitment started in January 2015 and continued till April 2015. Data was collected by the principle investigator by a face to face interview using an interviewer administered questionnaire during house to house visit. All the participants were given an appointment for DEXA scan in CMC. They were picked up from the village and taken to CMC for the scan on the day of appointment. Blood samples also were taken during their visit to CMC to test for serum albumin, serum creatinine, serum calcium and phosphate.

4.4 Inclusion criteria

Elderly men who were between 65 and 80 years of age and not bed ridden, residing in the villages which are selected for the study from Kaniyambadi block was eligible for the study.

4.5 Exclusion criteria

Bed-ridden patients were excluded from the study.

4.6 Variables in the study

The questionnaire had five parts

1) Sociodemographic details such as religion, socioeconomic status, marital status

2) FRAX-WHO fracture risk assessment tool which includes age, height ,weight, BMI (Body Mass Index), previous history of fracture, parent with fractured hip, current smoking status, h/o glucocorticoid intake, rheumatoid arthritis, any evidence of secondary osteoporosis, alcohol intake

3) IPAQ (International Physical Activity Questionnaire) short version for assessment of the level of physical activity

4) Dietary calcium intake (24 hour recall)

5) Laboratory investigations for assessment of serum level of calcium, phosphate, albumin and creatinine

Definition of each of the variables used in the study is given below in Table 4.1

Table 4.1 Definition of each of the variables used in the study

Variable	Definition
Height	Height of the patient measured in cm by an inch tape
Weight	Weight of the patient measured in kg by a bathroom weighing scale
BMI	Computed using the formulae weight in kg/height in meter ^2
Age	Age of the patient as told by him
SES	The socioeconomic status of the patient as calculated using Kuppuswamy score
Religion	Whether the patient was Hindu, Christian or Muslim
Marital status	Whether the patient was married, single, separate or a widower
Osteoporosis	BMD T-score of –2.5 or below the young normal mean for men.
Previous fracture	A previous fracture denotes more accurately a previous fracture in adult life occurring spontaneously, or a fracture arising from trauma which, in a healthy individual, would not have resulted in a fracture.
Parent with fractured hip	a history of hip fracture in the patient's mother or father
Current smoking	whether the patient is current smoker
Glucocortocoids use	Current use of oral glucocorticoids or has been using oral glucocorticoids for > 3 months at a dose of prednisolone of 5 mg daily or more (or equivalent doses of other glucocorticoids)
Rheumatoid arthritis:	Whether the patient is a known case of Rheumatoid arthritis
Secondary osteoporosis	Any of the diseases such as type I diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or, chronic malnutrition, or malabsorption and chronic liver disease which is associated with osteoporosis
Alcohol 3 or more units/day	Ingestion of 3 or more units of alcohol daily (one measure of spirits =30ml)
Marital status	whether the patient is married/separated/widower/single
Physical activity	Physical activity assessed using the International Physical Activity Questionnaire (IPAQ-Short Version).
Dietary calcium intake	Calcium intake of the patient per day
S.Calcium	The serum calcium level of the patient measured in mg/dl. During analysis was dichotomized as low or normal using 8.3mg/dl as cut off
S.Phosphate	The serum phosphate level of the patient measured in mg/dl .(normal range: 2.5-4.6mg/dl)
S.Albumin	The serum Albumin level of the patient measured in gm/dl. (normal range: 3.5-5 gm/dl)
S.Creatinine	The serum creatinine level of the patient measured in mg/dl. During analysis it was dichotomized as high or normal using 1.4mg/dl as cut off

4.7 Data sources and measurement

The details for sources of each variable and details of methods of assessment are described in the following Table 4.2.

Table 4.2 Sources of each variable and details of methods of assessment

Variable	**Data source /measurement**
Height	Measured during home visit using an inch tape
Weight	Measured during home visit using a bathroom weighing scale
BMI	Computed using the formulae weight in kg/height in meter ^2
Age	Questionnaire
Socioeconomic status	Questionnaire
Religion	Questionnaire
Marital status	Questionnaire
Osteoporosis	Dexa
Previous fracture	Questionnaire
Parent with fractured hip	Questionnaire
Current smoking	Questionnaire
Glucocortocoids use	Questionnaire
Rheumatoid arthritis:	Questionnaire
Secondary osteoporosis	Questionnaire
Alcohol 3 or more units/day	Questionnaire
Marital status	Questionnaire
Socioeconomic status	Questionnaire
Physical activity	Questionnaire
Dietary calcium intake	Questionnaire
S.Calcium	Laboratory investigation
S.Phosphate	Laboratory investigation
S.Albumin	Laboratory investigation
S.Creatinine	Laboratory investigation

4.8 Sample size calculation

n=4*P*Q/d^2

where P is the prevalence of osteoporosis (5)

P=45%

Q=100-P=55

d=9

=4*45*55/9^2

=122

Applying a design effect of 1.5 = 183

4.9 Data collection

Patients who fulfilled the inclusion criteria were included in the study. The principle investigator conducted house visits in the thirteen villages of Kaniyambadi block which were chosen by simple random sampling. In each village approximately 15-20 elderly men were chosen by simple random sampling. The principle investigator during the house visit filled in the interviewer administered questionnaire.

4.9.1 Questionnaire

Questionnaire had five parts

1) Sociodemographic details

2) FRAX_WHO fracture risk assessment tool

3) IPAQ short version for assessment of the level of physical activity

4) Dietary calcium intake (24 hour recall)

5) Laboratory investigations for determination of serum level of calcium, phosphate, albumin and creatinine. Blood sample was collected during their visit to the hospital. Albumin correction for calcium was done using the formulae:

"Corrected calcium = [(4-albumin)*0.8+actual calcium]"

Bone Mineral Density was assessed by DEXA scan.

4.9.2 DEXA Scan

Prior appointment was obtained for DEXA scan. The people who were recruited into the study were taken to CMC Vellore for dexa scan of femur and lumbar spine. In this study Bone mineral density was measured on a Hologic Dual energy X-Ray absorptiometry (DEXA) machine (Discovery A- QDR 4500) which has a one pass single sweep scanning system for better quality and precision.

4.9.3 Ascertainment of other risk factors

4.9.3.1 Socioeconomic factors

Factors such as education, occupation of the patient and the head of the family were collected. The total income of the family was also obtained during the interview. These were coded based on the Kuppusamy's socioeconomic scale. The score for education ranged from one to seven and the score for occupation ranged from one to ten. SES was computed based on the Kuppusamy's modified SES scale (2014) using the three variables.SES was classified into five categories namely lower, upper lower, lower middle, upper middle and upper.

4.9.3.2 Body Mass Index

Weight and height were taken at the time of home visit using a bathroom weighing scale and an inch tape respectively. For the purpose of analysis BMI was categorized into high and low taking 25 as the cut off as BMI more than 25 is defined as overweight.

4.9.3.3 FRAX®

To evaluate the fracture risk of patients WHO has developed a tool called FRAX® tool. This tool utilizes individual patient models that use the risks associated with clinical risk factors as well as bone mineral density (BMD) at the femoral neck. Depending on population based cohorts from Europe, North America, Asia and Australia the FRAX model was developed. It is computer generated and freely

available from the internet (Annexure 2). The FRAX algorithm gives the ten year probability of fracture. It gives both 10 year hip fracture probability and 10 year major osteoporotic fracture probability (clinical spine, forearm, hip or shoulder fracture).

4.9.3.4 IPAQ

IPAQ was used to assess physical activity undertaken in four domains such as vigorous physical activity, moderate physical activity, walking and sitting. Frequency (measured in days per week) and duration (time per day) for each specific type of activity were collected separately. The level of activity was calculated by weighting each activity by its energy requirements defined in METS (METS which is the "Metabolic Equivalent of Task" are the multiples of the resting metabolic rate) which gives a score in MET-minutes. MET minute was a product of the MET score and the minutes performed. MET minutes score are equivalent to kilocalories for a 60Kg person.

4.9.3.4.1 MET values and Formula for calculation of Met-minutes

[Source: Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ) - Short Form, Version 2.0. April 2004 (52)]

"Walking MET-minutes/week

= 3.3 * walking minutes * walking .days.

Moderate MET-minutes/week

= 4.0 * moderate-intensity activity minutes * moderate days

Vigorous MET-minutes/week

= 8.0 * vigorous-intensity activity minutes * vigorous-intensity days" (52)

Three levels of physical activity were defined to classify population. The categories are

i) HEPA active(Health Enhancing Physical Activity)

ii) minimally active

iii) inactive

Health Enhancing Physical Activity (HEPA-Category 3): This category included people who exceeded the minimum public health physical activity recommendations. People in this group will be active at least 1.5 to 2 hrs in a day. Subjects who fit into the following criteria were included in this group:

i) "vigorous-intensity activity on at least 3 days achieving a minimum of at least 1500 MET-minutes/week **OR**

ii) 7 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 3000 MET-minutes/week" (52)

Minimally active (Category 2): The people who belonged to this category have physical activity above the minimum level recommended for adults in current public health recommendation.

Subjects fulfill at least one of the following 3 criteria:

1) "3 or more days of vigorous activity of at least 20 minutes per day OR
2) 5 or more days of moderate-intensity activity or walking of at least 30 minutes per day OR
3) 5 or more days of any combination of walking, moderate-intensity or vigorous intensity activities achieving a minimum of at least 600 MET-min/week" (52).

Inactive category: This category of people has the lowest level of physical activity. Individuals who did not meet criteria for category 2 or 3 were categorized as insufficiently active or category 1.

4.9.3.4.2 Continuous score for IPAQ

Another method of expressing the IPAQ score in the study was reporting it as a continuous score. The total MET minutes was calculated for each person and expressed as median MET minutes.

A combined total physical activity MET-min/week was calculated using the formula:

"Total physical activity MET-min/week

=Walking + Moderate + Vigorous MET-min/week scores" (52)

IPAQ sitting question

It is an extra question which is not part of any scoring for total physical activity.

4.9.3.5 Nutritional Status

Twenty four hour diet recall of the patient was collected by the PI at the time of data collection. This was performed to assess the daily calcium intake of the patient. The PI (Principal Investigator) was blinded regarding the BMD status of the patient at the time of data collection.

4.10 Data entry and analysis

Data entry was done in Epidata version 3.1. Analysis was done in SPSS version 16.0.

5. RESULTS

5.1 Sociodemographic profile

A total of 180 men were included in the study. The distribution of the study population by age is described in the table below.

Table 5.1 Description of the study population by age

Age group(years)	Frequency	Percent
65-70	97	53.9
71-75	54	30
76-80	29	16.1
Total	180	100

Among the study population, 53.9% were in the 65 to 70 years group, 30% between 71 to 75 years and 16.1% between 76 and 80 years.

Table 5.2 Description of the study population by education

Education	Frequency	Percent
Nil	37	20.6
Primary school	59	32.8
Middle school	43	23.9
High school	31	17.2
Intermediate	5	2.8
Under graduate / Post graduate	5	2.8
Total	180	100

In the study population, 77.3% had studied up to middle school or less, while only 2.8% had proceeded on to college education [Table 5.2].

Table 5.3 Description of the study population by their previous occupation

Category	Frequency	Percent
Unskilled	49	27.2
Semiskilled	7	3.9
Skilled	25	13.9
Farmer	87	48.3
Semi professional	1	0.6
Professional	11	6.1
Total	180	100

The highest proportion of the study population were in agriculture (48.3%) and unskilled or manual labour (27.2%) [Table 5.3].

Table 5.4 Description of the study population by marital status

Category	Frequency	Percent
Married	161	89.4
Single	2	1.1
Separated	1	0.6
Widower	16	8.9
Total	180	100

Almost 90% of the subjects were married, while 9% were widowed [Table 5.4].

Religion - 99% of the subjects were Hindu by religion.

Significant past medical history and life style

30% of the subjects had a previous history of fracture. 6% of the subject had a parent who fractured a hip. 22.8% of the subjects were active smokers. 10.6% of the subjects consumed 3 or more units of alcohol per day.

Table 5.5 Description of the study population by socioeconomic status

Category	**Frequency**	**Percent**
Lower	0	0
Upper lower	68	37.9
Lower middle	71	39.4
Upper middle	35	19.4
Upper	6	3.3
Total	180	100

None of the subjects were in the lower socioeconomic group and majority were in the lower middle (39.4%) and upper lower (37.8%) categories respectively [Table 5.5].

5.2 Body Mass Index

Table 5.6 Distribution of BMI among the study population

BMI (Kg/m^2)	**Frequency**	**Percent**
≤18.49	32	17.8
18.5-24.99	104	57.8
25.0-29.99	36	20.0
≥30	8	4.4
Total	180	100

BMI was categorized into underweight (≤18.49), normal (18.5-24.99), over weight (25.0-29.99) and obese (≥30). 57.8% had a normal BMI, 17.8% were underweight, 20% were overweight and 4.4% were obese [Table 5.6].

5.3 Physical activity

Table 5.7 Distribution of physical activity among the study population

Category	Frequency	Percent
Inactive (0-599MET mins/week)	17	9.4
Minimally active (600-2999MET mins /week)	53	29.4
Health enhancing physical activity (≥3000MET min/ week)	110	61.1

Physical activity was analyzed using the IPAQ questionnaire and MET minutes per week calculated for each subject. It was categorized into inactive group (0-599MET minutes per week); minimally active (600-2999MET minutes per week) and Health enhancing physical activity (≥3000 MET minutes per week).

61.1% of the subjects were in the Heath enhancing physical activity (HEPA) category, 29.4% in the minimally active category and 9.4% in the inactive category [Table 5.7].

Table 5.8 Description of some of the study variables

Category	**Mean (Std Dev)**	**Median**
Age (years)	70.89(4.54)	70
Weight (kg)	59.79(13.14)	59.25
Height (cm)	164.18(5.82)	164.25
BMI(Kg/m^2)	22.14(4.05)	21.75
MET minutes per week	6679(6829)	4158
Daily dietary calcium intake(mg)	188(4.36)	180

The mean age of the subjects were 70.89 years (SD: 4.54years) and the median was 70years. The mean weight and standard deviation was 59.79Kg and 13.14Kg respectively. The median weight was 59. 25Kg. The mean height was 164.18cm and the standard deviation was 5.82cm. The median height was 164.25cm. The mean BMI was 22.14Kg/m^2 with a standard deviation of 4.05Kg/m^2 and a median of 21.75Kg/m^2 [Table 5.8].

5.4 Dietary calcium intake

The daily calcium intake of the subjects was assessed using a 24 hour dietary recall questionnaire. The average daily calcium intake was 188mg per day with a standard deviation was 4.36mg/day. The median was 180mg. This is much lower than the RDA (Recommended Dietary Allowance) which is 1200mg/day.

5.5 Biochemical parameters

Table 5.9 Description of Biochemical Parameters

Variable	Mean(SD)	Median
Serum Calcium (Normal Range:8.3-10.4mg/dl)	8.821(0.497)	8.79
Serum Phosphorus (Normal Range:2.5-4.6mg/dl)	3.32(0.833)	3.20
Serum Albumin (Normal Range:3.5-5g/dl)	4.19(0.38)	4.20
Serum Creatinine (Normal Range:0.7-1.4 mg/dl)	0.97(0.34)	0.90
BMD Lumbar Spine(g/cm^2)	0.967(0.215)	0.937
BMD Femoral neck(g/cm^2)	0.702(0.157)	0.705

The serum levels of Calcium, Phosphorous, Albumin and Creatinine were assessed. The mean serum calcium was 8.821mg/dl (SD: 0.497) with a median of 8.79mg/dl. The mean and SD of serum phosphorous was 3.32(0.833) mg/dl and the median was 3.20 mg/dl. The mean and standard deviation of serum albumin was 4.19(0.38) mg/dl and the median was 4.20mg/dl. The mean and standard deviation of serum creatinine is 0.97(0.34) mg/dl and the median is 0.90 mg/dl. The mean and standard deviation of Bone Mineral Density for lumbar spine was 0.967(0.215) g/cm^2 and the median was0.937g/cm^2. The mean and SD of Bone Mineral Density for femoral neck was 0.702 g/cm^2 and 0.157 g/cm^2 respectively. The median BMD of femoral neck was 0.705 g/cm^2 [Table 5. 9].

5.6 T-score for hip and lumbar spine

The histograms for T score for hip and lumbar spine were found to be normally distributed. [Figure 5.1& 5.2]

Figure 5.1 Histogram of hip T-score

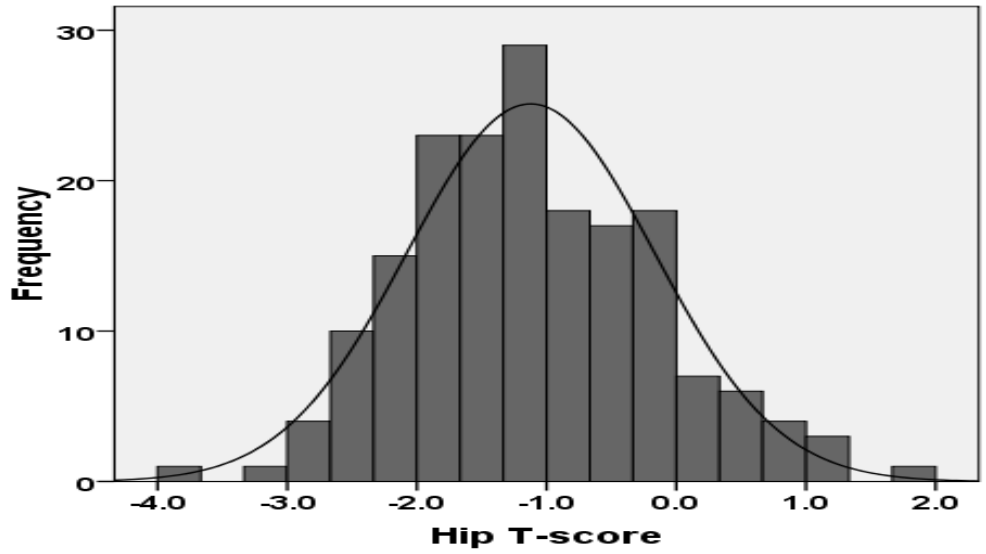
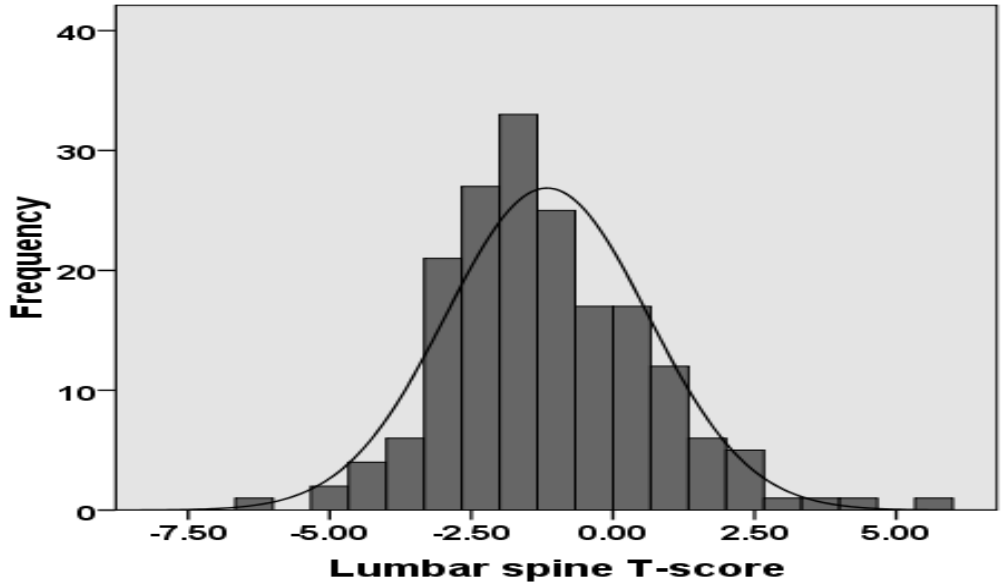
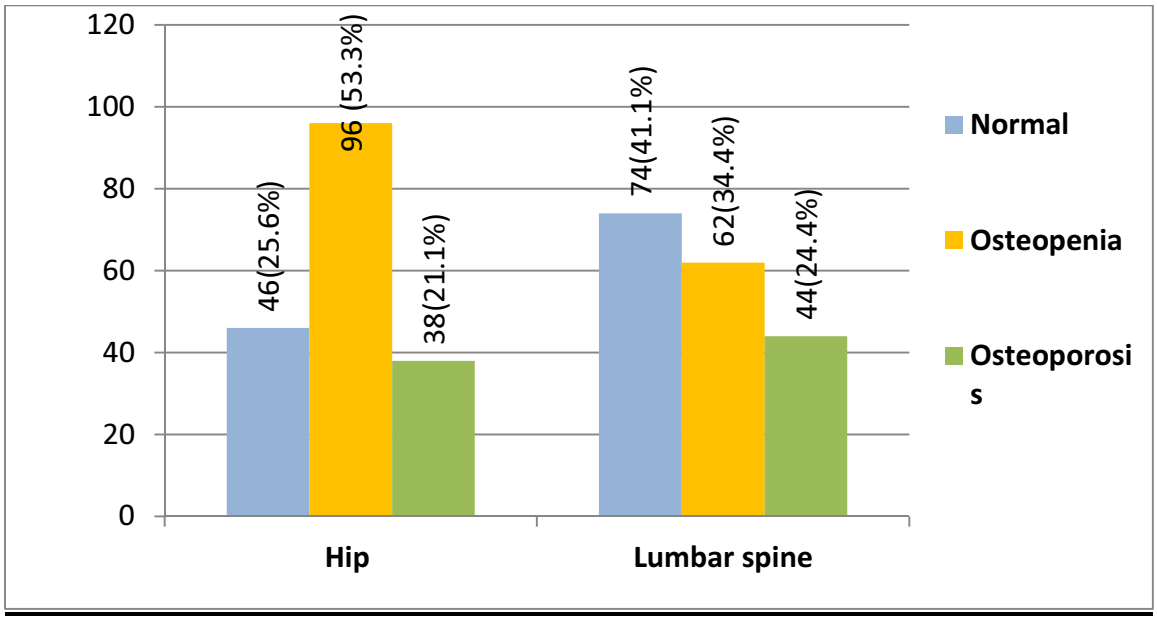


Figure 5.2 Histogram of lumbar spine T- score



5.7 Prevalence of osteoporosis

Figure 5.3 Prevalence of osteoporosis in hip and lumbar spine



In the hip region 25.6% had normal BMD, while 53.3% were osteopenic and 21.1% had osteoporosis. In the lumbar spine, 41.1% had normal BMD, 34.4% were osteopenic and 24.4% were osteoporotic [Figure 5.3].

- Proportion of subjects with normal BMD in both hip and lumbar spine: 16.7%(n=30)
- Proportion of subjects with osteopenia in both the sites: 19.4%(n=35)
- Proportion of subjects with osteoporosis in both the sites: 11.1%(n=20)
- Prevalence of **osteoporosis in either hip or lumbar spine or both: 34.4% (95%CI: 27.31% to 41.48%)**
- Prevalence of **osteopenia alone in either hip or lumbar spine or both: 48.9 % (95%CI: 41.45% to 56.35%)**

5.8 Fracture risk assessment

A 10 year major osteoporotic fracture (in the proximal part of the humerus, the wrist, or the hip or a clinical vertebral fracture**)** and hip fracture risk assessment were done in subjects with osteopenia. It was calculated by the FRAX WHO fracture risk assessment tool which utilizes clinical data such as age, gender, history of smoking, alcoholism, use of steroids, history of previous fracture, and history of parent hip fracture along with the femoral neck BMD.

It was found that none of the 88 subjects with osteopenia have a major osteoporotic fracture risk of more than 20% while 6 (6.8%) have >3% chance for hip fracture.

5.9 Pearson's/spearman's correlation between BMD and various risk factors

Table 5.10 Correlation coefficient between BMD and various risk factors

Variable	Femoral neck BMD		Hip BMD		Lumbar spine BMD	
	Correlation coefficient	p value	Correlation coefficient	p value	Correlation coefficient	p value
Weight	0.396	**<0.001**	0.421	**< 0.001**	0.404	**< 0.001**
Height	0.224	**0.002**	0.132	0.072	0.130	0.082
Age	-0.212	**0.004**	-0.145	0.052	0.17	0.825
BMI	0.375	**< 0.001**	0.428	**< 0.001**	0.393	**< 0.001**
SES	0.078	0.300	0.111	0.137	0.058	0.440
Serum Calcium	0.107	0.154	0.103	0.167	0.059	0.431
Serum phosphate	-0.025	0.744	-0.080	0.288	-0.044	0.554
Serum creatinine	-0.037	0.618	-0.006	0.941	0.162	**0.030**
Serum albumin	0.244	**0.001**	0.249	**0.001**	0.262	**< 0.001**
Total physical activity(MET minutes per week)	0.120*	0.110	0.133	0.075	-0.003	0.964
Dietary calcium intake per day	0.115	0.125	0.132	0.078	0.108	0.149

* Spearman's correlation

Correlation coefficient was calculated for various factors such as weight, height, age, BMI, socioeconomic status, serum levels of calcium, phosphate, creatinine, albumin, total physical activity and dietary calcium with femoral neck BMD, hip BMD and lumbar spine BMD.

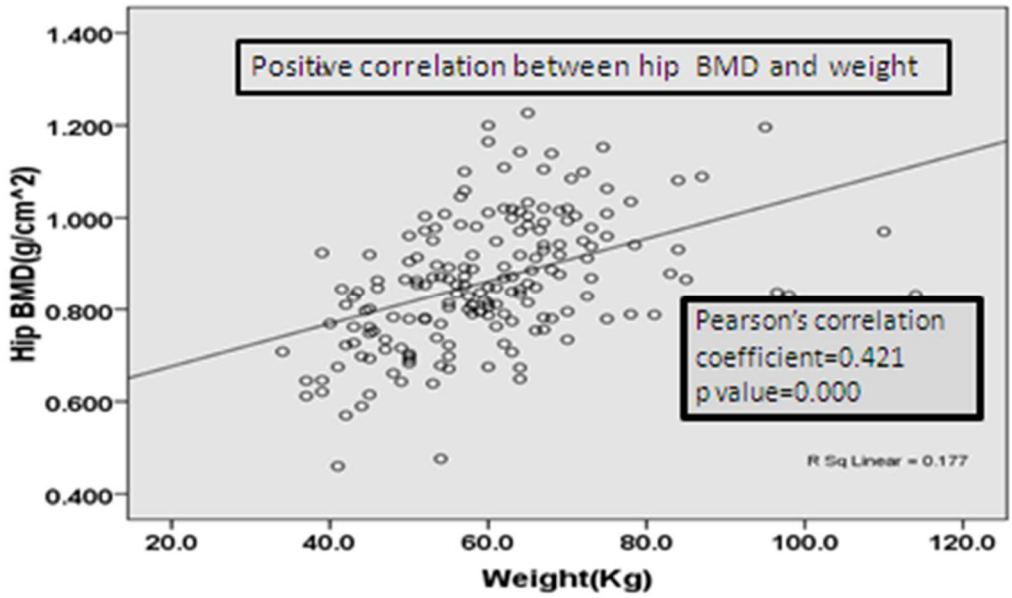
It was found that weight, BMI and serum albumin positively correlated with BMD in all the three areas (hip, femoral neck and lumbar spine) which was statistically significant.

Statistically significant positive correlation between height and BMD was found only in the femoral neck [Table 5.10].

Age was found to be negatively correlated with femoral neck BMD and it was statistically significant. There was a statistically significant correlation between serum creatinine and lumbar spine BMD.

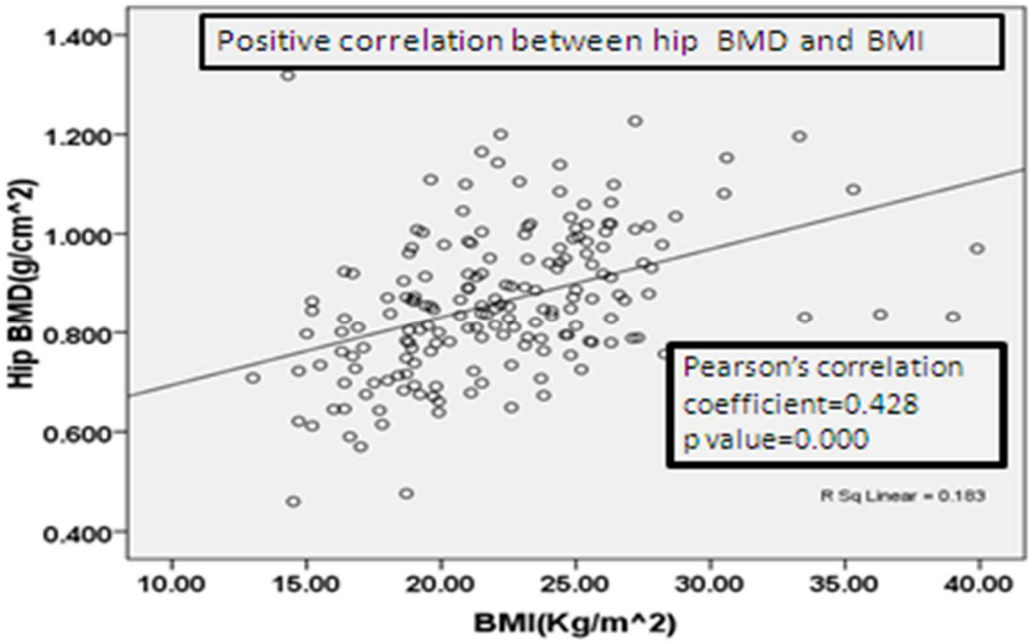
There was no statistically significant correlation between BMD and Socioeconomic status, serum calcium, serum phosphorous, total physical activity (MET minutes per week) or daily dietary calcium intake.

Figure 5.4 Scatter plot between hip BMD and weight



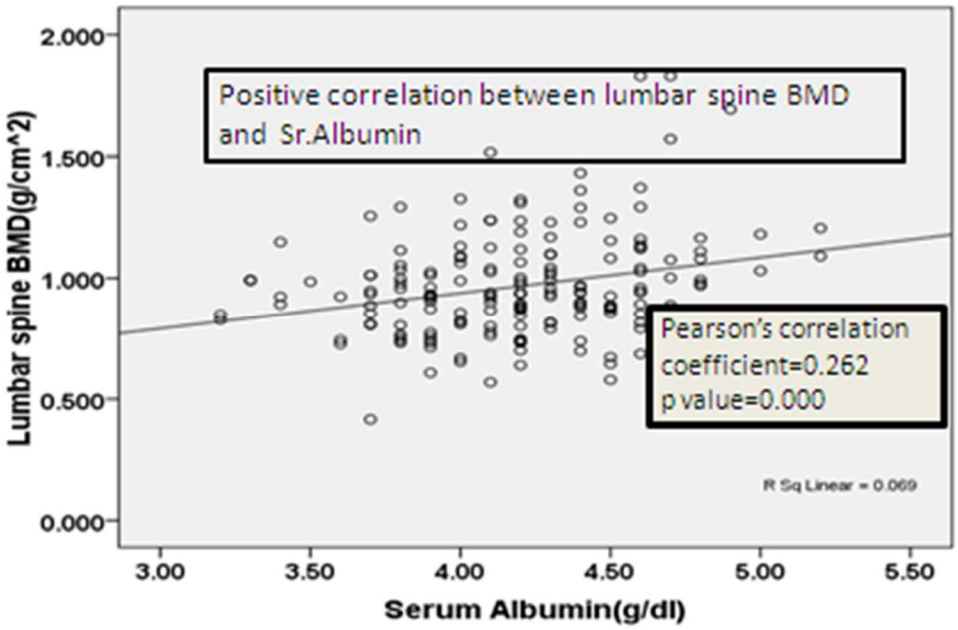
There is significant positive correlation between BMD and weight with Pearson's correlation coefficient of 0.421 and a p value < 0.001[Figure 5. 4]

Figure 5.5 Scatter plot between hip BMD and BMI



Similarly there is positive correlation between hip BMD and BMI with a Pearson's correlation of 0.428 and a p value of < 0.001 [Figure 5.5].

Figure 5.6 Scatter plot between lumbar spine BMD and Serum Albumin



On plotting a scatter plot between lumbar spine BMD and serum albumin, it was seen that there was a positive correlation between the two with a Pearson's correlation coefficient of 0.262 and a p value of < 0.001 [Figure 5.6].

5.10 UNIVARIATE ANALYSIS

Associations between osteoporosis and various risk factors

Table 5.11 Association between osteoporosis and sociodemographic factors

RISK FACTORS	Osteoporosis Present	No Osteoporosis	OR (95% CI)	P VALUE
Age				
Age up to 70	32(33%)	65(67%)	0.870 (0.470-1.611)	0.657
Age >70	30(36.1%)	53(63.9%)		
SES				
Lower SES	24(35.3%)	44(64.7%)	1.062 (0.564-2.000)	0.852
Middle and upper SES	38(33.9%)	74(66.1%)		
Marital status				
Separated/widower/divorced	11(57.9%)	8(42.1%)	2.966 (1.125-7.818)	0.023
Currently married	51(31.7%)	110(68.3%)		
Education				
Nil	17(45.9%)	20(54.1%)	1.851 (0.886-3.867)	0.099
Literate	45(31.5%)	98(68.5%)		
Previous occupation				
Unskilled	17(34.7%)	32(65.3%)	1.015 (0.509-2.024)	0.966
Semiskilled and above	45(34.4%)	86(65.6%)		

Univariate analysis between age and osteoporosis was computed. The cut off for age was taken as 70 years as it was the median age and it was found that there is no statistically significant association between age and osteoporosis [Odds ratio and 95%CI:0.870 (0.470-1.611) p value=0.657].

Similarly socioeconomic status was dichotomized into low SES and middle/upper SES and it was found that there is no statistically significant association between SES and osteoporosis [Odds ratio and 95%CI: 1.062 (0.564-2.000) p value =0.852].

Previous occupation of the subjects were dichotomized into unskilled and semiskilled or above and it was found that there is no statistically significant association between the two [Odds ratio and 95%CI: 1.015(0.509-2.024) and p value=0.966].

Marital status was dichotomized into currently married and separated/widower/divorced and it showed a statistically significant association between the two suggesting that there is higher chance of osteoporosis in subjects who are separated/widower/divorced than those who are currently married [Odds ratio and 95% CI: 2.966 (1.125-7.818) and a p value of 0.023].

Education was categorized into no education and literate. It was found that there is a higher chance of osteoporosis in people who are not educated than those

who are educated [Odds Ratio and 95% CI: 1.851 (0.886-3.867)], however it was not statistically significant (p value =0.099) [Table 5.11].

Weight was categorized into less than 60 kg and more than 60 kg as the cut off based on the median. It was found that men weighing less than 60 kg had a 4.143 times increased risk for osteoporosis when compared to men who weighed more than 60 kg and it was statistically significant [Odds Ratio and 95% CI: 4.143 (2.121-8.093) and p value <0.001]

Table 5.12 Association between BMI and osteoporosis

Category of BMI (Kg/m²)	**Osteoporosis present**	**No Osteoporosis**	**Chi square**	**p value**
<18.5	23 (71.9%)	9 (28.1%)	28.26	<0.001
18.5-25.0	32 (30.8%)	72 (69.2%)		
≥25 .0	7 (15.9%)	37 (84.1%)		

Chi square test was performed between BMI and osteoporosis. BMI was categorized into underweight (BMI<18.5 Kg/m²), normal (BMI 18.5 Kg/m²-25.0 Kg/m²) and overweight/obese (BMI≥25.0 Kg/m²). It was found that there was a statistically significant difference between the BMI categories and osteoporosis with a p value of <0.001 [Table 5.12].

Association between osteoporosis and biochemical factors

Table 5.13 Association between osteoporosis and biochemical factors

RISK FACTORS	Osteoporosis Present	No Osteoporosis	OR (95% CI)	P VALUE
Serum albumin (g/dl)				
Serum Albumin<=4.0	29(48.8%)	33(53.2%)	2.264 (1.193-4.296)	0.012
Serum albumin>4.0	33(28%)	85(72%)		
Serum phosphate (mg/dl)				
Phosphorus >2.5	55(34%)	107(66%)	0.808 (0.297-2.200)	0.676
Phosphorus ≤2.5	7(38.9%)	11(61.1%)		
Serum Creatinine (mg/dl)				
S.creatinine > 1.4	5(38.5%)	8(61.5%)	1.206 (0.377-3.856)	0.768
S.creatinine ≤ 1.4	57(34.1%)	110(65.9%)		
Corrected serum calcium (mg/dl)				
Corrected calcium <= 8.20	5(41.7%)	7(58.3%)	1.416 (0.430-4.662)	0.566
Corrected calcium > 8.20	56(33.5%)	111(66.5%)		

Serum albumin was dichotomized into less than 4g/dl and more than 4 g/dl and it was found that people with a low serum albumin had a 2.26 times increased risk for osteoporosis than people who had serum albumin more than 4 g/dl and it was statistically significant [Odds Ratio and 95%CI: 2.264 (1.193-4.296) and p value: 0.012].

However there was no statistically significant association between serum creatinine [Odds Ratio and 95% CI: 1.206 (0.377-3.856) and p value:0.768], serum Phosphate[Odds Ratio and 95% CI: 0.808 (0.297-2.200) and p value:0.676], serum calcium [Odds Ratio and 95% CI: 1.416 (0.430-4.662) and p value:0.566] and physical activity[Odds Ratio and 95% CI:1.096 (0.584-2.056) and p value:0.775] with osteoporosis. Results of the univariate analysis of the various biochemical parameters are summarized in Table 5.13.

Association between osteoporosis and other risk factors

Table 5.14 Association between osteoporosis and other risk factors

RISK FACTORS	Osteoporosis Present	No Osteoporosis	OR (95% CI)	P VALUE
Health enhancing physical activity				
No Health Enhancing Physical Activity	25(35.7%)	45(64.3%)	1.096 (0.584-2.056)	0.775
Health enhancing physical activity present	37(33.6%)	73(66.4%)		
Smoking				
Smoking - Yes	18(43.9%)	23(56.1%)	1.69 (0.828-3.447)	0.147
Smoking - No	44(31.7%)	95(68.3%)		
Previous fracture				
Yes	19(35.2%)	35(64.8%)	1.048 (0.537-2.046)	0.891
No	43(34.1%)	83(65.9%)		
Parent hip fracture				
Yes	3(30%)	7(70%)	0.806 (0.201-3.234)	0.761
No	59(34.7%)	111(65.3%)		
Alcohol				
Alcohol intake - Yes	7(36.8%)	12(63.2%)	1.124 (0.419-3.018)	0.816
Alcohol intake- No	55(34.2%)	106(65.8%)		
BMI				
BMI <25	55(40.4%)	81(59.6%)	3.589 (1.493-8.631)	0.003
BMI>=25		37(84.1%)		

BMI was dichotomized into <18.5Kg/m^2 and ≥18.5Kg/m^2 and it was found that under weight subjects have a seven times higher risk for osteoporosis than normal/overweight/obese subjects and it is statistically significant.[odds ratio and 95% CI: 7.142 (3.04 to 16.76) and p value: <0.001].

Alcohol intake was not significantly associated with osteoporosis [Odds Ratio and 95% CI: 1.124 (0.419-3.018) and p value: 0.816].

Similarly smoking [Odds ratio and 95% CI: 1.69 (0.828-3.447) ;p value:0.147] history of previous fracture[Odds ratio and 95% CI :1.048 (0.537-2.046) and p value=0.891] and history hip fracture in parent [Odds ratio and 95%CI : 0.806 (0.201-3.234) ;p value:0.761] also were not significantly associated with osteoporosis [Table 5.14]

5.11 Linear regression

Association between femoral neck BMD and various risk factors

Linear regression was performed taking BMD of femoral neck and lumbar spine as the dependent variable and other factors such as age, BMI, Serum albumin, marital status and education as independent variables.

Table 5.15 Linear regression between femoral neck BMD and risk factors for osteoporosis

Variable	Beta coefficient	p value	95% CI
Age	-0.012	0.379	-0.040 to 0.015
BMI	0.074	**<0.001**	0.046 to 0.102
Serum albumin	0.449	**0.007**	0.127 to 0.772
Marital status	-0.062	0.761	-0.462 to 0.338
Education	0.215	0.162	-0.087 to 0.516

Table 5.15 shows the linear regression between femoral neck BMD and the various risk factors for osteoporosis. As age increases by one year the femoral neck BMD decreases by 0.012 g/cm^2 ,however it is not statistically significant(p value=0.379)

There was a statistically significant association between femoral neck BMD and BMI. As BMI increases by 1 Kg/m^2, femoral neck BMD increases by 0.074 g/cm^2 and it was statistically significant with a p value of <0.001.

Similarly there was a statistically significant association between femoral neck BMD and serum albumin. As serum albumin increases by 1g/dl, femoral neck BMD increases by 0.449g/cm^2 and it is statistically significant (p value=0.007).

Marital status (p value=0.761) and education of the subject (p value=0.162) were not significantly associated with femoral neck BMD.

Association between lumbar spine BMD and various risk factors

Linear regression was performed between lumbar spine BMD and various other risk factors for osteoporosis [Table 5.16].

Table 5.16 Linear regression between lumbar spine BMD and risk factors for osteoporosis

Variable	Beta coefficient	p value	95% CI
Age	0.006	0.068	0.000 to 0.012
BMI	0.018	**<0.001**	0.012 to 0.025
Serum albumin	0.120	**0.002**	0.044 to 0.196
Marital status	-0.060	0.213	-0.154 to 0.035
Education	0.035	0.335	-0.036 to 0.106

BMI and serum albumin were significantly associated with lumbar spine BMD. As BMI increases by 1kg/m^2 lumbar spine BMD increases by 0.018g/cm^2 (p value is < 0.001).

Similarly as serum albumin increases by 1g/dl lumbar spine BMD increases by 0.120 g/cm^2 (p value=0.002).

Age (p value=0.068), marital status (p value=0.213) and education (p value=0.335) were not significantly associated with lumbar spine BMD.

5.12 Logistic regression

Table 5.17 Multiple logistic regression showing factors affecting osteoporosis

Variable	Osteoporosis present	No osteoporosis	Unadjusted OR (95% CI)	p value	Adjusted OR (95% CI)	p value
BMI						
BMI<18.5	23(71.9%)	9(28.1%)	7.142 (3.04 to 16.76)	<0.001	8.389 (3.354-20.98)	**<0.001**
BMI≥18.5	39(26.4%)	109(73.6%)				
Age						
Age ≥70	35(34.7%)	66(65.3%)	1.021 (0.550-1.898)	0.947	0.918 (0.458-1.841)	0.810
Age <70	27(34.2%)	52(65.8%)				
Marital status						
Separated/ widowed/ divorced	11(57.9%)	8(42.1%)	2.966 (1.125-7.818)	0.023	2.457 (0.792-7.628)	0.120
Married	51(31.7%)	110 (68.3%)				
Education						
Nil	17(45.9%)	20(54.1%)	1.851 (0.886-3.867)	0.099	2.431 (1.050-5.628)	**0.038**
Literate	45(31.5%)	98(68.5%)				
Serum Albumin						
Albumin ≤4	29(48.8%)	33(53.2%)	2.264 (1.193-4.296)	0.012	2.569 (1.253-5.267)	**0.010**
Albumin >4	33(28%)	85(72%)				

Multiple logistic regression was performed taking all the variables which had a p value less than 0.10 in the univariate analysis and age was also included as it is a physiological factor which can influence bone mineral density. Results of logistic regression are summarized in the Table 5.17.

After adjusting for the possible confounding factors, it was found that literacy, BMI and serum albumin were still significantly associated with osteoporosis.

People who had no education had a 2.43 times increased risk for development of osteoporosis when compared to educated men (95% CI and p value: 1.050-5.628; 0.038).

Men who had a BMI less than 18.5 had an 8.3 times increased risk for osteoporosis with a 95% confidence interval between 3.354-20.98 and p value of < 0.001.

Serum albumin level of less than 4g/dl had a 2.56 times increased risk for osteoporosis with a 95% confidence interval of 1.253-5.267 and a p value of 0.010.

Age [Odds Ratio and 95%CI: 0.918 (0.458-1.841); p value: 0.810] and marital status [Odds Ratio and 95%CI:2.457 (0.792-7.628); p value: 0.120] did not have any significant association with osteoporosis.

6. DISCUSSION

Osteoporosis has mostly been considered to be a problem affecting women. However, recent evidence suggests that male osteoporosis is an important emerging public health problem. This study was aimed at exploring the prevalence of osteoporosis and the risk factors for the same among elderly ambulatory men in South India. This was a community based study, thus the results is a true representation of the prevalence in the community.

Prevalence of osteoporosis

The table given below [Table 6.1] shows a comparison between the present study and earlier studies on the prevalence of osteoporosis in men.

Table 6.1 Comparison of prevalence of osteoporosis in men

Study	**Age group studied (years)**	**Prevalence**
Melton et al (14)	>50	19%
Agarwal et al (53)	>50	8.5%
Shetty et al (5)	>60	45%
Present study	65-80	34.4%

In our study, about one third of men [34.4% (95%CI: 27.31% to 41.48%)] had osteoporosis at any one site, either hip or lumbar spine. The prevalence of men with osteopenia was also high in this study. One in every two patients had osteopenia in at least one site [48.9% (95%CI: 41.45% to 56.35%)]. Only 16.7% of the patients had a normal bone mineral density in both the sites.

Prevalence of osteoporosis in healthy Indian men above 50 years of age as published in a study done by Agarwal et al was 8.5%. The prevalence of osteopenia in the same study was 42% (53). Another study done in by Shetty et al in South India the reported prevalence of osteoporosis was 20% in men above 50 years (5).The mean age of the population of that study was 58.8years when compared to 70.89 years in the current study which might be one of the factors contributing to the difference in prevalence. However, the prevalence of osteoporosis in men above 60 years in the same study (Shetty et al) was 45%. A study done by Melton et al in Rochester showed a prevalence rate of osteoporosis in men above 50 years to be 19% (14).

The estimated bone loss in men with aging is 1percent per year (54). Trabecular thinning in men is attributed to bone remodeling with aging (55). Bone Mineral Density in men start to decline in men from 30 to 40 years of age (5). This study showed a negative correlation between age and BMD in the femoral neck [Pearson's correlation coefficient=-0.212 and p value=0.0.004].

Body Mass Index

Table 6.2 Comparison of prevalence of osteoporosis in different BMI categories

BMI	Normal	Overweight	Obese
Nottingham fracture liaison study (56)	40.40%	24.90%	13.40%
Present study	57.80%	20%	4.40%

In a cross sectional study which used data collected from the Nottingham Fracture Liaison Service, the prevalence of osteoporosis varied across different categories of BMI. It was found to be 13.4%, 24.9%, and 40.4% in the obese, overweight and normal category respectively (56) [Table 6.2]. Distribution of prevalence of osteoporosis in different BMI groups in the present study was 4.4%, 20% and 57.8% in the obese, overweight and normal category respectively. The difference in prevalence between different populations could be due to factors such as genetic, dietary and environment differences. Table 6.3 summarizes the findings from different studies which assessed the association between BMI and osteoporosis.

Table 6.3 Association between BMI and osteoporosis in different studies summarized

Study	Study subjects	Finding
Salamat et al(57)	230 men 50-79 years old	Obesity decreased the risk for osteoporosis
The Framingham study (58)	Elderly male and female participants of the Framingham osteoporosis study	Recent weight and BMI explained variance in BMD in men
Fawzy et al (59)	Men and women 25 to 80years	Lower BMI is a risk factor for low BMD.
Nguyen et al(60)	1075 women and 690 men aged 60 or above	Higher weight or BMI associated with higher BMD
Present study	180 men 65 to 80 years	Men with BMI less than 18.5 had an 8.3 times increased risk for osteoporosis

This study showed an increase in BMD with increasing BMI in keeping with several other studies. In an Iranian study which investigated the relation between BMI, weight and BMD in Iranian men it was found that the age-adjusted odds ratio was 4.4 for men with a BMI <25 in comparison to men with BMI more than 25 (57). In another study done by Nguyen et al to assess the effect of dietary calcium, physical activity and body mass index on osteoporosis it was found that , among subjects who belonged to the lowest tertile of BMI, quadriceps strength and dietary calcium intake, 40% of the men were classified as osteoporotic (60). In a study done in Australia among Iranian women it was found that advancing age, low BMI and smoking were independently associated with lumbar spine and femoral neck BMD (61). A study done at University hospitals Coventry and Warwickshire (UK) showed that the beneficial effect of BMI on bone mineral density exists up to a BMI of 35Kg/m^2beyond which there is no further increase in BMD (62). The Framingham study suggested that the load on the weight bearing bones is responsible for the strong effect of weight on Bone Mineral Density (63). The other factors which are responsible are increased peak bone mass and higher circulating estradiol in the blood (5). However, studies done among urban black south African women have shown that lean body mass, and not fat mass is favorable for bone health(64).Visceral Adipose Tissue (VAT) is deleterious to bone health. The characteristic features of male obesity such as decreased growth hormone and testosterone may be detrimental whereas estradiol is protective (65).

Serum albumin

Table 6.4 Association of BMD and serum albumin in different studies summarized

Study	Finding
Monaco et al (66)	Positive correlation of BMD and serum albumin
Rancho Bernado study (67)	No association between the BMD and serum albumin
Present study	Low serum albumin is an independent risk factor for osteoporosis

Protein deficiency is harmful for bone health. However the association between BMD and serum albumin is debatable. This study showed that the low serum albumin is an independent risk factor for osteoporosis (Odds Ratio and 95%CI: 2.56; 1.253-5.267 and a p value of 0.010.). Monaco et al found a positive correlation between albumin and BMD measured in the total femur ($r = 0.50$, $p < 0.01$), femur neck ($r = 0.52$, $p < 0.01$), intertrochanteric area ($r = 0.52$, $p < 0.01$) and Ward's triangle ($r = 0.49$, $p < 0.01$) in men (66). However in the Rancho Bernado study which investigated the relation between serum albumin and BMD in community dwelling white men and women between the age group of 50 to 95yeras, it was found that there was no age independent association between BMD and serum albumin (67). Table 6.4 summarizes the findings from different studies which assessed the association between serum albumin and osteoporosis.

Univariate analysis in this study showed that people who were either single, divorced or widowed were at higher risk for development for osteoporosis [Odds Ratio and 95%CI:2.966 (1.125-7.818) and a p value of 0.023]. However this association was not significant after adjusting for the potential confounding factors. This finding is in corroboration with finding from the systematic review which showed that there is strong evidence for association between being married or living with someone and reduced risk for osteoporotic fractures (68).

In a cross sectional study which evaluated the association between poverty, bone density, fragility fractures and metabolic syndrome in Southern European women, it was found that lower socioeconomic status was associated with lower levels of BMD at the lumbar spine and higher prevalence of fragility fractures (69). In our study even though there was no statistically significant association between osteoporosis and socioeconomic status, it was found that there is significant association between education of the patient and development of osteoporosis. Osteoporosis was found more in people with no education and it was statistically significant [Odds Ratio and 95%CI: 2.431(1.050-5.628)]. In a systematic review which evaluated the evidence of low socioeconomic status as an independent risk factor for osteoporosis, it was found that there is contradictory evidence for the relation between osteoporotic fractures and level of income and education (68). Another systematic review which assessed the association SES status and BMD in

adults it was evident that there is a positive association between educational attainment and BMD in women (70).

Table 6.5 Association between physical activity and BMD from different studies summarized

Study	Findings
Nguyen et al (56)	Physical activity index was not significantly associated with femoral neck BMD in men
Moayyaeri et al (71)	Moderate to vigorous physical activity was associated with 45% risk reduction for hip fracture in men
Present study	No association between physical activity and osteoporosis

Physical activity and osteoporosis did not have any association in this study. In a review article which assessed the causal association between physical activity and osteoporotic fractures, it was evident that moderate to vigorous physical activity was associated with 45% (95%CI:31%-56%) risk reduction for hip fracture in men (71). However positive effect of physical activity on BMD is of doubtful magnitude for prevention of fracture risk (71) . Review of cross sectional studies shows that there is a positive correlation between BMD and exercise, and interventional studies suggest that high impact exercise is beneficial in increasing BMD (72). The findings from different studies which assessed the association between physical activity and osteoporosis are summarized in Table 6.5.

Smoking did not have any significant association with osteoporosis in this study. This was in contradiction to a meta-analysis investigating the relation between

smoking and osteoporosis which revealed that current smokers had reduced bone mass and increased fracture risk at the age of 50 years and above and this association remained significant even after adjusting for age, sex , body weight and years since menopause (73).

This study failed to find any significant association between alcohol consumption and the development of osteoporosis, as opposed to studies which suggest that alcoholism disrupts the calcium and bone homeostasis which results in decreased BMD and lead to fragility fractures (74). Ethanol may lead to osteoblastic dysfunction which causes reduced bone formation and mineralization (75).

In comparison with women, elderly men have more risk factors for osteoporosis and is associated with three to four times higher mortality in case of hip fractures (76,77). The financial burden associated with osteoporotic fracture is not only borne by the family of the patient but the country as a whole (5,78). Apart from the direct cost incurred on the treatment of these fractures it is essential to include the indirect cost in terms of large man hours lost by the patient as well as the care giver which is particularly important in developing countries like India (5,79).

7. LIMITATIONS

Of the several tools available to assess the physical activity, IPAQ which was suitable for use in the elderly, highly overestimates the level of physical activity and hence may not be the best tool to be used.

8. SUMMARY AND CONCLUSIONS

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Osteoporosis is an important cause of fracture in elderly men. Although the morbidity, mortality, and costs of osteoporosis have been well established in post menopausal women and elderly men, these consequences in older men have not been well studied in an Indian context. In our study we assessed the prevalence and risk factors for osteoporosis among elderly men. We studied 180 men between the age group of 65 to 80 years from Kaniyambadi block by simple random sampling. We found that elderly men have a high prevalence of osteoporosis. Prevalence of osteoporosis in elderly men in South India was 34.4% (95%CI: 27.31% to 41.48%) and the prevalence of osteopenia was 48.9% (95%CI: 41.45% to 56.35%). Low Body Mass Index (BMI), low serum albumin and lack of education were significantly associated with osteoporosis. Smoking, alcohol consumption, serum calcium, phosphate, creatinine, socioeconomic status, and previous history of fracture, were not significantly associated with osteoporosis.

In the coming years there will be an increase in the prevalence of osteoporosis owing to the aging population of India. As this is a silent disease which progresses to fracture without any symptoms, it is important to keep in mind the probable outcomes of fall in the elderly and devise strategies to prevent or reduce the impact of falls in this age group.

9. RECOMMENDATIONS

Osteoporosis is still under diagnosed in developing countries like India. Much work needs to be done in this field to create awareness regarding the disease which will be the first step in tackling this problem. The truth that one in three of all the hip fractures take place in men and that men have twofold increased risk of dying within a year after hip fracture is not given much consideration (80). Serious contemplation of the consequences of fracture in elderly men by clinicians and patients is the need of the hour

- We recommend screening of elderly men with high risk factors such as low BMI and low albumin levels for osteoporosis.
- Men should be encouraged to maintain adequate BMI to prevent the development of osteoporosis
- Food with high calcium and protein should be included in the diet of the elderly
- Calcium supplementation in men should be encouraged to prevent osteoporotic fracture

10. Bibliography

1. World Health Organization . Assessment of Fracture Risk and its Application to Screening for Postmenopausal Osteoporosis: Report of a World Health Organization Study Group. Geneva: World Health Organization; 1994. [cited 2014 Nov 11]. Available from: http://apps.who.int/iris/bitstream/10665/39142/1/WHO_TRS_843_eng.pdf?ua=1

2. Mithal A, Ebeling P. International Osteoporosis Federation. The Asia Pacific Regional audit: Epidemology, costs and burden of osteoporosis in 2013. [cited 2015 Sep 28]. Available from: http://www.iofbonehealth.org/sites/default/files/media/PDFs/Regional%20Audits/2013-Asia_Pacific_Audit_0_0.pdf

3. Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 1997;7(5):407–13.

4. Facts and Statistics | International Osteoporosis Foundation [Internet]. [cited 2014 Nov 10]. Available from: http://www.iofbonehealth.org/facts-statistics

5. Shetty S, Kapoor N, Naik D, Asha HS, Prabu S, Thomas N, et al. Osteoporosis in Healthy South Indian Males and the Influence of Life Style Factors and Vitamin D Status on Bone Mineral Density. J Osteoporos. 2014 Nov 11;2014:e723238.

6. Burge R, Dawson-Hughes B, Solomon DH, Wong JB, King A, Tosteson A. Incidence and Economic Burden of Osteoporosis-Related Fractures in the United States, 2005–2025. J Bone Miner Res. 2007 Mar 1;22(3):465–75.

7. Pawel Szulc and Mary L Bouxsein. Vertebral Fracture Initiative Part I; Overview of osteoporosis: Epidemiology and clinical management. [cited 2014 Nov 10]. Available from: http://www.iofbonehealth.org/sites/default/files/PDFs/Vertebral%20Fracture%20Initiative/IOF_VFI-Part_I-Manuscript.pdf

8. IQ Solutions I. Osteoporosis in Men [Internet]. [cited 2014 Nov 10]. Available from: http://www.niams.nih.gov/Health_Info/Bone/Osteoporosis/men.asp

9. Mithal A, Kaur P. Osteoporosis in Asia: a call to action. Curr Osteoporos Rep. 2012 Dec;10(4):245–7.

10. Prentice A. Diet, nutrition and the prevention of osteoporosis. Public Health Nutr. 2004 Feb;7(1a):227–43.

11. WHO Scientific Group On The Assessment Of Osteoporosis At Primary Health Care Level; Summary Meeting Report ;Brussels, Belgium, 5-7 May 2004 . [cited 2015 Jun 30]. Available from: http://www.who.int/chp/topics/Osteoporosis.pdf

12. Faisal-Cury A, Zacchello KP. Osteoporosis: prevalence and risk factors among > 49 year-old women in private practice environment. Acta Ortopédica Bras. 2007;15(3):146–50.

13. Paul T, Mruthyunjaya M, Shyamasunder A, Naik D, Rajaratnam S, Thomas N, et al. The diagnosis of osteoporosis among subjects of Southern Indian origin above 50 years of age: the impact of the indian council of medical research vs caucasian bone mineral density reference standards. Endocr Abstr. 2013 Mar 1;1–1.

14. Melton LJ, Atkinson EJ, O'Connor MK, O'Fallon WM, Riggs BL. Bone density and fracture risk in men. J Bone Miner Res Off J Am Soc Bone Miner Res. 1998 Dec;13(12):1915–23.

15. Melton LJ, Chrischilles EA, Cooper C, Lane AW, Riggs BL. Perspective. How many women have osteoporosis? J Bone Miner Res Off J Am Soc Bone Miner Res. 1992 Sep;7(9):1005–10.

16. Kanis JA, Johnell O, Oden A, Sembo I, Redlund-Johnell I, Dawson A, et al. Long-term risk of osteoporotic fracture in Malmö. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 2000;11(8):669–74.

17. Mithal A, Ebeling P. International Osteoporosis Federation. The Asia Pacific Regional audit: Epidemology, costs and burden of osteoporosis in 2013. [Internet].[cited 2014 Nov 22]. Available from: http://www.iofbonehealth.org/sites/default/files/media/PDFs/Regional%20Audits/2013-Asia_Pacific_Audit-India_0_0.pdf

18. Kaufman J-M, Reginster J-Y, Boonen S, Brandi ML, Cooper C, Dere W, et al. Treatment of osteoporosis in men. Bone. 2013 Mar;53(1):134–44.

19. Olszynski WP, Davison KS. Alendronate for the treatment of osteoporosis in men. Expert Opin Pharmacother. 2008 Feb;9(3):491–8.

20. Sambrook P, Cooper C. Osteoporosis. The Lancet. 2006 Jun 23;367(9527):2010–8.

21. European Prospective Osteoporosis Study (EPOS) Group, Felsenberg D, Silman AJ, Lunt M, Armbrecht G, Ismail AA, et al. Incidence of vertebral fracture in

europe: results from the European Prospective Osteoporosis Study (EPOS). J Bone Miner Res Off J Am Soc Bone Miner Res. 2002 Apr;17(4):716–24.

22. van Staa TP, Dennison EM, Leufkens HG, Cooper C. Epidemiology of fractures in England and Wales. Bone. 2001 Dec;29(6):517–22.

23. Tricco AC, Cogo E, Holroyd-Leduc J, Sibley KM, Feldman F, Kerr G, et al. Efficacy of falls prevention interventions: protocol for a systematic review and network meta-analysis. Syst Rev. 2013 Jun 6;2(1):38.

24. Clinicians guide to prevention and treatment of osteoporosis.National Osteoporosis Foundation. [Internet]. [cited 2015 Jun 29]. Available from: http://nof.org/files/nof/public/content/file/344/upload/159.pdf

25. Office of the Surgeon General (US). Bone Health and Osteoporosis: A Report of the Surgeon General [Internet]. Rockville (MD): Office of the Surgeon General (US); 2004 [cited 2015 Jun 29]. Available from: http://www.ncbi.nlm.nih.gov/books/NBK45513/

26. Colón-Emeric C, Kuchibhatla M, Pieper C, Hawkes W, Fredman L, Magaziner J, et al. The contribution of hip fracture to risk of subsequent fractures: data from two longitudinal studies. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 2003 Nov;14(11):879–83.

27. Mithal A, Bansal B, Kyer CS, Ebeling P. The Asia-Pacific Regional Audit-Epidemiology, Costs, and Burden of Osteoporosis in India 2013: A report of International Osteoporosis Foundation. Indian J Endocrinol Metab. 2014;18(4):449–54.

28. Rubenstein LZ. Falls in older people: epidemiology, risk factors and strategies for prevention. Age Ageing. 2006 Sep 1;35(suppl 2):ii37–41.

29. Dempster DW, Shane E, Horbert W, Lindsay R. A simple method for correlative light and scanning electron microscopy of human iliac crest bone biopsies: qualitative observations in normal and osteoporotic subjects. J Bone Miner Res Off J Am Soc Bone Miner Res. 1986 Feb;1(1):15–21.

30. Cooper C, Melton LJ. Epidemiology of osteoporosis. Trends Endocrinol Metab TEM. 1992 Aug;3(6):224–9.

31. Giusti A, Bianchi G. Male osteoporosis. Reumatismo. 2014;66(2):136–43.

32. Risk factors | Osteoporosis Australia [Internet]. [cited 2014 Nov 24]. Available from: http://www.osteoporosis.org.au/risk-factors

33. NIHSeniorHealth: Osteoporosis - Risk Factors [Internet]. [cited 2014 Nov 24]. Available from: http://nihseniorhealth.gov/osteoporosis/riskfactors/01.html

34. Osteoporosis Risk factors - Diseases and Conditions - Mayo Clinic [Internet]. [cited 2014 Nov 24]. Available from: http://www.mayoclinic.org/diseases-conditions/osteoporosis/basics/risk-factors/con-20019924

35. Jørgensen NR, Schwarz P, Holme I, Henriksen BM, Petersen LJ, Backer V. The prevalence of osteoporosis in patients with chronic obstructive pulmonary disease: a cross sectional study. Respir Med. 2007 Jan;101(1):177–85.

36. Singh Chahar P. Physiological basis of Growth and Development among Children and Adolescent in Relation to Physical Activity. Am J Sports Sci Med. 2014 Sep 23;2(5A):17–22.

37. Kujala UM, Kaprio J, Kannus P, Sarna S, Koskenvuo M. Physical activity and osteoporotic hip fracture risk in men. Arch Intern Med. 2000 Mar 13;160(5):705–8.

38. Correlation between Bone Mineral Density Measured by Dual-Energy X-Ray Absorptiometry and Hounsfield Units Measured by Diagnostic CT in Lumbar Spine [Internet]. [cited 2015 Aug 2]. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3873350/

39. Albanese CV, Diessel E, Genant HK. Clinical applications of body composition measurements using DXA. J Clin Densitom Off J Int Soc Clin Densitom. 2003;6(2):75–85.

40. Sharma et al. Preliminary screening of osteoporosis and osteopenia in urban women from Jammu using calcaneal QUS.[Internet]. [cited 2015 Aug 1]. Available from: http://www.bioline.org.br/pdf?ms06027

41. Stransky. Nutrition as Prevention and Treatment of Osteoporosis. Physiol Rev. 2009;58.

42. Tuck SP, Datta HK. Osteoporosis in the aging male: Treatment options. Clin Interv Aging. 2007 Dec;2(4):521–36.

43. Ringe JD, Orwoll E, Daifotis A, Lombardi A. Treatment of male osteoporosis: recent advances with alendronate. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 2002 Mar;13(3):195–9.

44. Orwoll E, Ettinger M, Weiss S, Miller P, Kendler D, Graham J, et al. Alendronate for the Treatment of Osteoporosis in Men. N Engl J Med. 2000 Aug 31;343(9):604–10.

45. Borgström F, Johnell O, Jönsson B, Zethraeus N, Sen SS. Cost effectiveness of alendronate for the treatment of male osteoporosis in Sweden. Bone. 2004 Jun;34(6):1064–71.

46. Boonen S, Orwoll ES, Wenderoth D, Stoner KJ, Eusebio R, Delmas PD. Once-weekly risedronate in men with osteoporosis: results of a 2-year, placebo-controlled, double-blind, multicenter study. J Bone Miner Res Off J Am Soc Bone Miner Res. 2009 Apr;24(4):719–25.

47. Sim I-W, Ebeling PR. Treatment of osteoporosis in men with bisphosphonates: rationale and latest evidence. Ther Adv Musculoskelet Dis. 2013 Oct;5(5):259–67.

48. Boonen S, Reginster J-Y, Kaufman J-M, Lippuner K, Zanchetta J, Langdahl B, et al. Fracture risk and zoledronic acid therapy in men with osteoporosis. N Engl J Med. 2012 Nov;367(18):1714–23.

49. Kurland ES, Cosman F, McMahon DJ, Rosen CJ, Lindsay R, Bilezikian JP. Parathyroid Hormone as a Therapy for Idiopathic Osteoporosis in Men: Effects on Bone Mineral Density and Bone Markers. J Clin Endocrinol Metab. 2000 Sep 1;85(9):3069–76.

50. Bilezikian JP. Combination anabolic and antiresorptive therapy for osteoporosis: opening the anabolic window. Curr Osteoporos Rep. 2008 Mar;6(1):24–30.

51. Cusano NE, Costa AG, Silva BC, Bilezikian JP. Therapy of Osteoporosis in Men with Teriparatide. J Osteoporos. 2011 Oct 25;2011:e463675.

52. Guidelines for Data Processing and Analysis of the International Physical Activity Questionnaire (IPAQ) - Short Form, Version 2.0. April 2004 [Internet]. [cited 2015 Oct 1]. Available from: http://www.institutferran.org/documentos/scoring_short_ipaq_april04.pdf

53. Agrawal NK, Sharma B. Prevalence of osteoporosis in otherwise healthy Indian males aged 50 years and above. Arch Osteoporos. 2013;8:116.

54. Heaney RP, Abrams S, Dawson-Hughes B, Looker A, Marcus R, Matkovic V, et al. Peak bone mass. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 2000;11(12):985–1009.

55. Riggs BL, Melton LJ, Robb RA, Camp JJ, Atkinson EJ, Peterson JM, et al. Population-Based Study of Age and Sex Differences in Bone Volumetric Density, Size, Geometry, and Structure at Different Skeletal Sites. J Bone Miner Res. 2004 Dec 1;19(12):1945–54.

56. Ong T, Sahota O, Tan W, Marshall L. A United Kingdom perspective on the relationship between body mass index (BMI) and bone health: a cross sectional analysis of data from the Nottingham Fracture Liaison Service. Bone. 2014 Feb;59:207–10.

57. Salamat MR, Salamat AH, Abedi I, Janghorbani M, Salamat MR, Salamat AH, et al. Relationship between Weight, Body Mass Index, and Bone Mineral Density in Men Referred for Dual-Energy X-Ray Absorptiometry Scan in Isfahan, Iran, Relationship between Weight, Body Mass Index, and Bone Mineral Density in Men Referred for Dual-Energy X-Ray Absorptiometry Scan in Isfahan, Iran. J Osteoporos J Osteoporos. 2013 Oct 3;2013, 2013:e205963.

58. Felson DT, Zhang Y, Hannan MT, Anderson JJ. Effects of weight and body mass index on bone mineral density in men and women: The framingham study. J Bone Miner Res. 1993 May 1;8(5):567–73.

59. Fawzy T, Muttappallymyalil J, Sreedharan J, Ahmed A, Alshamsi SOS, Al Ali MSSHBB, et al. Association between Body Mass Index and Bone Mineral Density in Patients Referred for Dual-Energy X-Ray Absorptiometry Scan in Ajman, UAE. J Osteoporos [Internet]. 2011 May 22 [cited 2015 Sep 25];2011. Available from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3135277/

60. Osteoporosis in Elderly Men and Women: Effects of Dietary Calcium, Physical Activity, and Body Mass Index - Nguyen - 2010 - Journal of Bone and Mineral Research - Wiley Online Library [Internet]. [cited 2015 Sep 20]. Available from: http://onlinelibrary.wiley.com/doi/10.1359/jbmr.2000.15.2.322/full

61. Baheiraei A, Pocock NA, Eisman JA, Nguyen ND, Nguyen TV. Bone mineral density, body mass index and cigarette smoking among Iranian women: implications for prevention. BMC Musculoskelet Disord. 2005 Jun 24;6(1):34.

62. Oldroyd A, Dubey S. The association between bone mineral density and higher body mass index in men. Int J Clin Pract. 2015 Jan 1;69(1):145–7.

63. Felson DT, Zhang Y, Hannan MT, Anderson JJ. Effects of weight and body mass index on bone mineral density in men and women: The framingham study. J Bone Miner Res. 1993 May 1;8(5):567–73.

64. Olusola F. Sotunde HSK. Lean Mass Appears to Be More Strongly Associated with Bone Health than Fat Mass in Urban Black South African Women. J Nutr Health Aging. 2015;

65. Bredella MA, Lin E, Gerweck AV, Landa MG, Thomas BJ, Torriani M, et al. Determinants of bone microarchitecture and mechanical properties in obese men. J Clin Endocrinol Metab. 2012 Nov;97(11):4115–22.

66. Di Monaco M, Vallero F, Di Monaco R, Mautino F, Cavanna A. Biochemical markers of nutrition and bone mineral density in the elderly. Gerontology. 2003 Feb;49(1):50–4.

67. Lunde AV, Barrett-Connor E, Morton DJ. Serum albumin and bone mineral density in healthy older men and women: the Rancho Bernardo Study. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 1998;8(6):547–51.

68. Brennan SL, Pasco JA, Urquhart DM, Oldenburg B, Hanna F, Wluka AE. The association between socioeconomic status and osteoporotic fracture in population-based adults: a systematic review. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 2009 Sep;20(9):1487–97.

69. Navarro M del C, Saavedra P, Jódar E, Gómez de Tejada MJ, Mirallave A, Sosa M. Osteoporosis and metabolic syndrome according to socio-economic status, contribution of PTH, vitamin D and body weight: The Canarian Osteoporosis Poverty Study (COPS). Clin Endocrinol (Oxf). 2013 May;78(5):681–6.

70. Metabolic Bone Diseases—Advances in Research and Treatment: 2012 Edition: ScholarlyBrief. ScholarlyEditions; 2012. 528 p.

71. Moayyeri A. The Association Between Physical Activity and Osteoporotic Fractures: A Review of the Evidence and Implications for Future Research. Ann Epidemiol. 2008 Nov;18(11):827–35.

72. Todd J, Robinson R. Osteoporosis and exercise. Postgrad Med J. 2003 Jun;79(932):320–3.

73. M I. [Osteoporosis and smoking]. Clin Calcium. 2005 Jul;15(7):156–8.

74. M K, S W. [Osteoporosis and alcohol intake]. Clin Calcium. 2005 Jan;15(1):102–5.

75. Diamond T, Stiel D, Lunzer M, Wilkinson M, Posen S. Ethanol reduces bone formation and may cause osteoporosis. Am J Med. 1989 Mar;86(3):282–8.

76. Diamond TH, Thornley SW, Sekel R, Smerdely P. Hip fracture in elderly men: prognostic factors and outcomes. Med J Aust. 1997 Oct 20;167(8):412–5.

77. Bliuc D, Nguyen ND, Milch VE, Nguyen TV, Eisman JA, Center JR. Mortality risk associated with low-trauma osteoporotic fracture and subsequent fracture in men and women. JAMA. 2009 Feb 4;301(5):513–21.

78. Qu B, Ma Y, Yan M, Wu H-H, Fan L, Liao D-F, et al. The economic burden of fracture patients with osteoporosis in western China. Osteoporos Int J Establ Result Coop Eur Found Osteoporos Natl Osteoporos Found USA. 2014 Jul;25(7):1853–60.

79. Malhotra N, Mithal A. Osteoporosis in Indians. Indian J Med Res. 2008 Mar;127(3):263–8.

80. Adler RA. Osteoporosis in men: a review. Bone Res [Internet]. 2014 Apr 29 [cited 2015 Sep 21];2. Available from: http://www.nature.com/articles/boneres20141

Annexure 1

SOCIODEMOGRAPHIC DETAILS

1.	NAME				
2.	ID NO.				
3.	VILLAGE				
4.	RELIGION				
5.	EDUCATION				
6.	Highest education				
7.	Occupation				
8.	Highest occupation				
9.	INCOME/month				
10.	MARITAL STATUS	Married	Single	Separated	Widower

FRAX-WHO FRACTURE RISK ASSESSMENT TOOL

1.	AGE /DATE OF BIRTH		
2.	WEIGHT (Kg)		
3.	HEIGHT(cm)		
4.	PREV. FRACTURE	NO	YES
5.	PARENT FRACTURED HIP	NO	YES
6.	CURRENT SMOKING	NO	YES
7.	GLUCOCORTICOIDS	NO	YES
8.	RHEUMATOID ARTHRITIS	NO	YES
9.	SECONDARY OSTEOPOROSIS	NO	YES
10.	ALCOHOL 3 OR MORE UNITS/DAY	NO	YES
11.	FEMORAL NECK BMD(g/cm^2)		

LABORATORY INVESTIGATIONS

1	S.CALCIUM	
2	S.PHOSPHATE	
3	s.vitamin D	
4	S.CREATININE	
5	S.ALBUMIN	

Short Last 7 Days Telephone IPAQ

READ: I am going to ask you about the time you spent being physically active in the last 7 days. Please answer each question even if you do not consider yourself to be an active person. Think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

READ: Now, think about all the *vigorous* activities which take *hard physical effort* that you did in the last 7 days. Vigorous activities make you breathe much harder than normal and may include heavy lifting, digging, aerobics, or fast bicycling. Think only about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities?

_____ Days per week [VDAY; Range 0-7, 8,9]

8. Don't Know/Not Sure

9. Refused

[**Interviewer clarification**: Think only about those physical activities that you do for at least 10 minutes at a time.]

[**Interviewer note**: If respondent answers zero, refuses or does not know, skip to Question 3]

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

__ __ Hours per day [VDHRS; Range: 0-16]
__ __ __ Minutes per day [VDMIN; Range: 0-960, 998, 999]
998. Don't Know/Not Sure

999. Refused

[**Interviewer clarification**: Think only about those physical activities you do for at least 10 minutes at a time.]

[**Interviewer probe**: An average time for one of the days on which you do vigorous activity is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, ask: "How much time in total would you spend **over the last 7 days** doing vigorous physical activities?"

__ __ Hours per week [VWHRS; Range: 0-112]

__ __ __ __Minutes per week [VWMIN; Range: 0-6720, 9998, 9999]

9998. Don't Know/Not Sure

9999. Refused

READ: Now think about activities which take *moderate physical effort* that you did in the last 7 days. Moderate physical activities make you breathe somewhat harder than normal and may include carrying light loads, bicycling at a regular pace, or doubles

tennis. Do not include walking. Again, think about only those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities?

____ Days per week [MDAY; Range: 0-7, 8, 9]

8. Don't Know/Not Sure

9. Refused

[**Interviewer clarification**: Think only about those physical activities that you do for at least 10 minutes at a time]

[**Interviewer Note**: *If respondent answers zero*, refuses or does not know, skip to Question 5]

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

__ __ Hours per day [MDHRS; Range: 0-16]

__ __ __ Minutes per day [MDMIN; Range: 0-960, 998, 999]

998. Don't Know/Not Sure

999. Refused

[**Interviewer clarification**: Think only about those physical activities that you do for at least 10 minutes at a time.]

[**Interviewer probe**: An average time for one of the days on which you do moderate activity is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, or includes time spent in multiple jobs, ask: "What is the total amount of time you spent over the **last 7 days** doing moderate physical activities?"

__ __ __ Hours per week [MWHRS; Range: 0-112]

__ __ __ __Minutes per week [MWMIN; Range: 0-6720, 9998, 9999]

9998. Don't Know/Not Sure

9999. Refused

READ: Now think about the time you spent walking in the last 7 days. This includes at work and at home, walking to travel from place to place, and any other walking that you might do solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

____ Days per week [WDAY; Range: 0-7, 8, 9]

8. Don't Know/Not Sure

9. Refused

[**Interviewer clarification**: Think only about the walking that you do for at least 10 minutes at a time.]

[**Interviewer Note**: *If respondent answers zero*, refuses or does not know, skip to Question 7]

6. How much time did you usually spend **walking** on one of those days?

__ __ Hours per day [WDHRS; Range: 0-16]

__ __ __ Minutes per day [WDMIN; Range: 0-960, 998, 999]

998. Don't Know/Not Sure

999. Refused

[**Interviewer probe**: An average time for one of the days on which you walk is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, ask: "What is the total amount of time you spent walking over **the last 7 days**?"

__ __ __ Hours per week [WWHRS; Range: 0-112]

__ __ __ __Minutes per week [WWMIN; Range: 0-6720, 9998, 9999]

9998. Don't Know/Not Sure

9999. Refused

READ: Now think about the time you spent sitting on week days during the last 7 days. Include time spent at work, at home, while doing course work, and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television.

7. During the last 7 days, how much time did you usually spend ***sitting*** on a **week day**?

__ __ Hours per weekday [SDHRS; 0-16]
__ __ __ Minutes per weekday [SDMIN; Range: 0-960, 998, 999]

998. Don't Know/Not Sure

999. Refused

[**Interviewer clarification**: Include time spent lying down (awake) as well as sitting]

[**Interviewer probe**: An average time per day spent sitting is being sought. If the respondent can't answer because the pattern of time spent varies widely from day to day, ask: "What is the total amount of time you spent *sitting* last **Wednesday**?"

__ __ Hours on Wednesday [SWHRS; Range 0-16]

__ __ __ Minutes on Wednesday [SWMIN; Range: 0-960, 998, 999]

998. Don't Know/Not Sure

999. Refused

Calcium intake study

Date:

Name : **Age :** **Hosp.No.:**

Height : **Weight :** **BMI :**

Health problem : **Pann chewing :** **Smoking :**

Form 1 : Meal Plan – 24 hrs recall

Meal	Time	What and how much?
Early morning		**Coffee / tea / milk / kanchi**
Break fast		**Idli / dosa / chappathi / poori / upma / chappathi / parotha / semia /**

		Chutney – coconut / groundnut / tomato / onion
Mid morning		**Coffee / tea / milk / kanchi / juice** **Biscuits (ordinary / cream / salt / butter)** **cream bun / bun butter & jam** **bread butter and jam / cake (cream / ordinary)** **Samoza / puff (veg / egg / mutton / chicken) / vadai / bajji**
Lunch		**Rice / sambar / rasam / karakulumbu** **Kurma / coconut kulumbu** **Muttan kulumbu / chicken kulumbu / fish kulumbu** **Mutton / chicken / fish / egg** **Carrot / beetroot / cauliflour / beans / lady's finger / drumstick / brinjal / avaraikai / cabbage / potato /**

		yam / colacacia **Greens – seeri / aria / murunga / manathakali / avathi / ponaangani**
Tea time		**Coffee / tea / milk / kanchi / juice** **Biscuits (ordinary / cream / salt / butter)** **cream bun / bun butter & jam** **bread butter and jam / cake (cream / ordinary)** **Samoza / puff (veg / egg / mutton / chicken) / vadai / bajji**
Dinner		**Lunch pattern –** **Breakfast pattern -**

Bed time		**Milk**
In between snacks & beverages		**Fruits – apple / banana / grapes / orange / mosambi / sapota / mango / pomogra / pineapple / jackfruit /**
Type of oil used -		**g.nut / coconut / gingelly / sunflower / dalda / butter / ghee**

Annexure 2

1. பெயர் :
2. எண் :
3. கிராமம் :
4. சமயம் :
5. கல்வி :
6. உயர் கல்வி :
7. தொழில் :
8. உயர் தொழில் :
9. மாத வருமானம் :
10. திருமண நிலை : திருமணமாகியவர் / திருமணமாகாதவர் / பிரிந்து வாழ்பவர் / விதவை

பிராக்ஸ்-WHO எலும்பு முறிவு பாதிப்பு குறித்த ஆய்வு சாதனம்

1. வயது/பிறந்த தேதி :

2. இடை (கிலோ கிராம்) :

3. உயரம் (சென்டி மீட்டர்) :

4. முன்பு எலும்பு முறிவு ஏற்பட்டதா : இல்லை/ஆம்

5. பெற்றோருக்கு இடுப்பு எலும்பு முறிவு ஏற்பட்டதா : இல்லை/ஆம்

6. தற்போது புகைபிடிப்பீரா : இல்லை / ஆம்

7. குளுகோ கார்ட்டி காய்டுஸ் :

8. ருமட்டைடு ஆர்தரைட்டியா : இல்லை / ஆம்

9. செகன்டரி ஒஸ்டியோ போரோஸ் : இல்லை / ஆம்

10. மதுபானம் மூன்று (அ) அதற்கு அதிகம் : இல்லை / ஆம்

11. ஃபீமோரால் நெக பிளம்டீ (g/cm^2)

பரிசோதனை

1. எஸ்.கால்சியம்

2. எஸ்.பாஸ்பேட்

3. எஸ்.கிரியேடினன்

4. எஸ்.ஆல்புமின்

படிக்கவும் : கடந்த ஏழு நாட்களில், தங்கள் எவ்வளவு நேரம் உடல் உழைப்பு உண்டாக்கும் செயல்களை செய்தீர்கள். உடல் உழைப்பு செய்யாதவராக இருந்தாலும், தயவு செய்து கேள்விகளுக்கு பதில் அளிக்கவும். நீங்கள். என்னென்ன செயல்களை செய்கிறீர்கள் உங்கள் வேலை இடத்தில் வீட்டில், நிலத்தில், பிரயாணத்தில் மற்றும் உங்கள் எஞ்சிய நேரத்தில் எந்த

பொழுதுபோக்கு, உடல்பயிற்சி (அல்லது) வேலையாட்டில் ஈடுபட்டீர்கள் என்பதை யோசிக்கவும்.

படிக்கவும் : நீங்கள் கடந்த ஏழு நாட்களில் செய்த கடின உடல் உழைப்பு மிகுந்த கடுமையான செயல்கள் யாவையும் நினைத்துக் கொள்ளுங்கள். கடுமையான செயல்கள், உங்களை சராசரிக்கும் அதிகமாக மூச்சு இறைக்க வைக்கும், அவை வலுதுங்குவது, மண் வெட்டுவது, உடற்பயிற்சி (அல்லது) வேகமாக சைக்கிளிங்கு. இந்த உடல் உழைப்பு குறைந்தது 10 நிமிடமாவது செய்திருக்க வேண்டும்.

1. இந்த கடந்த ஏழு நாட்களில் எத்தனை நாட்கள் கடின உடல் வேலை செய்தீர்கள்?

   _____ எத்தனை நாட்கள் ஒரு வாரத்தில்

   8. தெரியவில்லை / சரியாக தெரியவில்லை

   9. சொல்ல மறுப்பது

நேர்முகம் காண்போர் தெளிவுபடுத்த வேண்டிய : (குறைந்தது 10 நிமிடமாவது செய்த உடல் உழைப்புள்ள வேலை மட்டும் சொல்லவும்).

நேர்முகம் காண்போரின் குறிப்பு : பதில் கொடுப்பார், ஒன்றும் பதில் கொடுக்கவில்லை, பதில் சொல்ல மறுத்தாலோ அல்லது தெரியவில்லை என்றால் கேள்வி மூன்றுக்கு (3) போகவும்.

2. ஒரு நாளில், நீங்கள் எவ்வளவு நேரம் கடினமாக உடல் உழைப்பு மிக்க வேலையை செய்வீரர்கள்?

   _____ ஒரு நாளில் எத்தனை மணி நேரம்

   _____ ஒரு நாளில் எத்தனை நிமிடம்

   998. தெரியவில்லை / சரியாக தெரியவில்லை

   999. பதில் மறுப்பது.

நேர்முகம் காண்போர் தெளிவுபடுத்த வேண்டியது :

சராசரியாக ஒரு நாளைக்கு எவ்வளவு நேரம் கடினமாக உடல் உழைப்பு மிகுந்த வேலையை செய்வீரர்கள் என்று கேட்கவும். பதில் கொடுக்க முடியவில்லை எனில், காரணம் அவர் செலவு செய்யும் நேரம் ஒவ்வொரு நாளும் வேறுபடும். ஆதலால், இப்படி கேட்கவும், எவ்வளவு நேரம் மொத்தமாக கடந்த ஏழு நாட்களில், கடினமான உடல் உழைப்பு மிகுந்த வேலையை செய்தீர்களா?

படிக்கவும் :

கடந்த ஏழு நாட்களில், நீங்கள் மிதமான (ஓரளவு) உடல் உழைப்புள்ள வேலைகள் என்னென்ன செய்தீர்கள் என்று நாபகபடுத்துங்கள். மிதமான (ஓரளவு) உடல் உழைப்பு உள்ள வேலைகள் செய்யும்போது ஓரளவு மூச்சு இறைக்கும். குறைவான இடையுள்ள அமையை துக்குவது, சைக்கிள் மிதமான வேகத்தில் ஓட்டுவது (அல்லது) இரட்டையார் டென்னிஸ் ஆடுவதும் ஆகியவை இதில் அடங்கும். இதில் நடப்பது உள்ளடங்காது. குறிப்பாக, இந்த அனைத்து உடல் உழைப்பு ஒவ்வொன்றும் குறைந்தது 10 நிமிடமாவது செய்திருக்க வேண்டும்.

3. கடந்த ஏழு நாட்களில், நீங்கள் எத்தனை நாட்கள் மிதமான உடல் உழைப்புள்ள வேலைகளை செய்தீர்கள்?

_____ வாரத்தில் எத்தனை நாட்கள்

8. தெரியவில்லை / சரியாக தெரியவில்லை

9. பதில் கொடுக்க மறுப்பது.

4. நீங்கள் எத்தனை மணிநேரம் மிதமான உடல் உழைப்புள்ள வேலைகளை ஒரு நாளில் செய்வீர்கள்?

_____ ஒரு நாளில் எத்தனை மணி நேரம்

_____ ஒரு நாளில் எத்தனை நிமிடங்கள்

998. தெரியவில்லை / சரியாக தெரியவில்லை

999. பதில் கொடுக்க மறுப்பது.

நேர்முகம் காண்போர் தெளிவுபடுத்த வேண்டியது : குறைந்தது 10 நிமிடமாவது. செய்த உடல் உழைப்புள்ள வேலையை மட்டும் சொல்லவும்.

நேர்முகம் காண்போர் தெளிவுபடுத்த வேண்டியது : குறைந்தது 10 நிமிடமாவது செய்த உடல் உழைப்புள்ள வேலை மட்டும் சொல்லவும்.

நேர்முகம் காண்போரின் குறிப்பு : பதில் கொடுப்போர் ஒன்றும் பதில் கொடுக்கவில்லை, பதில் சொல்ல மறுத்தாலோ (அ) தெரியவில்லை என்றால் கேள்வி (5) செல்லவும்.

நேர்முகம் காண்போரின் கேள்விகள்

சராசரியாக எவ்வளவு மணி நேரம் ஒரு நாளைக்கு நீங்கள் மிதமான உடல் உழைப்புள்ள வேலைகளை செய்வீர்கள். சரியான பதில் கொடுக்க முடியவில்லை என்றால் காரணம் அவர் ஒவ்வொரு வேலைக்கு செலவு செய்யும் நேரம். ஒவ்வொரு நாளும் வேறுபடும் மற்றும் பற்பல வேலைகள் செய்வதும் அடங்கும். ஆதலால், கடந்த ஏழு நாட்களில் மொத்தமாக எவ்வளவு நேரம் மிதமான உடல் உழைப்புள்ள வேலைகள் செய்தீர்கள் என கேட்கவும்?

_____ எத்தனை மணி நேரம் ஒரு வாரத்தில்

_____ எத்தனை நிமிடங்கள் ஒரு வாரத்தில்

9998. தெரியவில்லை / சரியாக தெரியவில்லை

9999. பதில் கொடுக்க மறுப்பது.

படிக்கவும் :

நீங்கள் கடந்த ஏழு நாட்களில், எத்தனை நேரம் நடப்பதற்கு செலவு செய்தீர்கள். இதில் வேலை இடத்தில் நடப்பது, மற்றும் வீட்டில், பிரயாணத்தின் போது, பொழுது போக்காக நடப்பது, விளையாட்டின் போது உடல் பயிற்சியின் போது (அ) ஓய்வு நேரம் கிடைக்கும் போது நடப்பதும் அடங்கும்.

5. கடந்த ஏழு நாட்களில், எத்தனை நாட்கள் பத்து நிமிடமாவது நடந்தீர்கள்?

_____ எத்தனை நாட்கள் / ஒரு வாரத்தில்

8. தெரியவில்லை / சரியாக தெரியவில்லை.

9. பதில் கொடுக்க மறுப்பது.

நேர்முகம் காண்போர் தெளிவுபடுத்த வேண்டியது : குறைந்தது 10 நிமிடமாவது செய்த உடல் உழைப்புள்ள வேலை மட்டும் சொல்லவும்.

நேர்முகம் காண்போரின் குறிப்பு : பதில் கொடுப்போர் ஒன்றும் பதில் கொடுக்கவில்லை, பதில் சொல்ல மறுத்தாலோ (அ) தெரியவில்லை என்றால் கேள்வி (7) செல்லவும்.

6. ஒரு நாளைக்கு எவ்வளவு நேரம் நடப்பதற்க செலவு செய்வீர்கள்?

_____ ஒரு நாளைக்கு எத்தனை நேரம்

_____ ஒரு நாளைக்கு எவ்வளவு நிமிடம்

998. தெரியவில்லை / சரியாக தெரியவில்லை

999. பதில் கொடுக்க மறுப்பது.

(நேர்முகம் காண்போர் மேலும் கேட்க வேண்டியது)

சராசரியாக, ஒரு நாளைக்கு எவ்வளவு நேரம் நடப்பீர்கள் என்பதை தெரிய விரும்புகிறேன். ஒரு வேளை, சரியான பதில் கிடைக்கவில்லை எனில், அதற்கு காரணம் ஒவ்வொரு நாளும் நடப்பதற்கு செலவிடும் நேரம் வேறுபடும். ஆதலால் இப்படி கேட்கவும், கடந்த ஏழு நாட்களில் மொத்தமாக எவ்வளவு நேரம் நடக்கிறீர்கள்?

_____ ஒரு வாரத்திற்கு எத்தனை நேரம்.

_____ ஒரு வாரத்திற்கு எத்தனை நிமிடம்.

9998. தெரியவில்லை / சரியாக தெரியவில்லை

9999. பதில் கொடுக்க மறுப்பது.

படிக்கவும் :

கடந்த ஏழு நாட்களில், நீங்கள் எவ்வளவு நேரம் பகல் நேரங்களில் உட்கார்ந்திருந்தீர்கள். இதில் வேலை இடங்களில் உட்கார்ந்தது, வீட்டில், மற்றும் பொழுதுபோக்கும் போது உட்கார்ந்திருக்கும் நேரமும் அடங்கும். இதில் மேஜையில் உட்கார்ந்திருதல், நண்பர்களை சந்தித்தல், படித்தல் அல்லது உட்கார்ந்திருத்தல், படுத்துக் கொண்டு தொலைக்காட்சி பார்த்தாலும் அடங்கும்.

7. கடந்த எழு நாட்களில், எத்தனை நேரம் ஒரு வாரத்தில் பகல் நேரங்களில் உட்கார்ந்திருப்பீர்கள்?

_____ ஒருவாரத்தில் எத்தனை நேரம்

_____ ஒருவாரத்தில் எத்தனை நிமிடம்

தெரியவில்லை/சரியாக தெரியவில்லை

பதில் கொடுக்க மறுத்தல்

(நேர்முகம் காண்பேர் தெளிவுபடுத்த வேண்டியது)

படுத்திருத்தல் மற்றும் உட்காருதல் நேரமும் அடங்கும்.

(நேர்முகம் காண்போர் மேலும் கேட்க வேண்டியது)

சராசரி ஒரு நாளில் எவ்வளவு நேரம். உட்கார்ந்திருப்பீர்கள். பதில் கொடுப்போர் கேள்வி தர முடியவில்லை எனில், காரணம் அவர் நேரம் செலவு செய்யும் அளவு ஒவ்வொரு நாளும் வேறுபடும். ஆதலால் இப்படி கேட்கவும், கடந்த புதன்கிழமை, நீங்கள் மொத்தமாக எவ்வளவு நேரம் உட்கார்ந்திருந்தீர்கள்.

_____ புதன் அன்று செலவு செய்த நேரம்

_____ புதன் அன்று செலவு செய்த நிமிடங்கள்

998. தெரியவில்லை/சரியாக தெரியவில்லை

999. பதில் கொடுக்க மறுப்பு

கால்சியம் உள்ளேடுத்தல் பற்றிய ஆய்வு

தேதி :

பெயர் : வயது : ஆய்வு எண்.

உயரம் : இடை : பி.எம்.ஐ :

உடல் பிரச்சனை : பான்மெள்ளுவது :

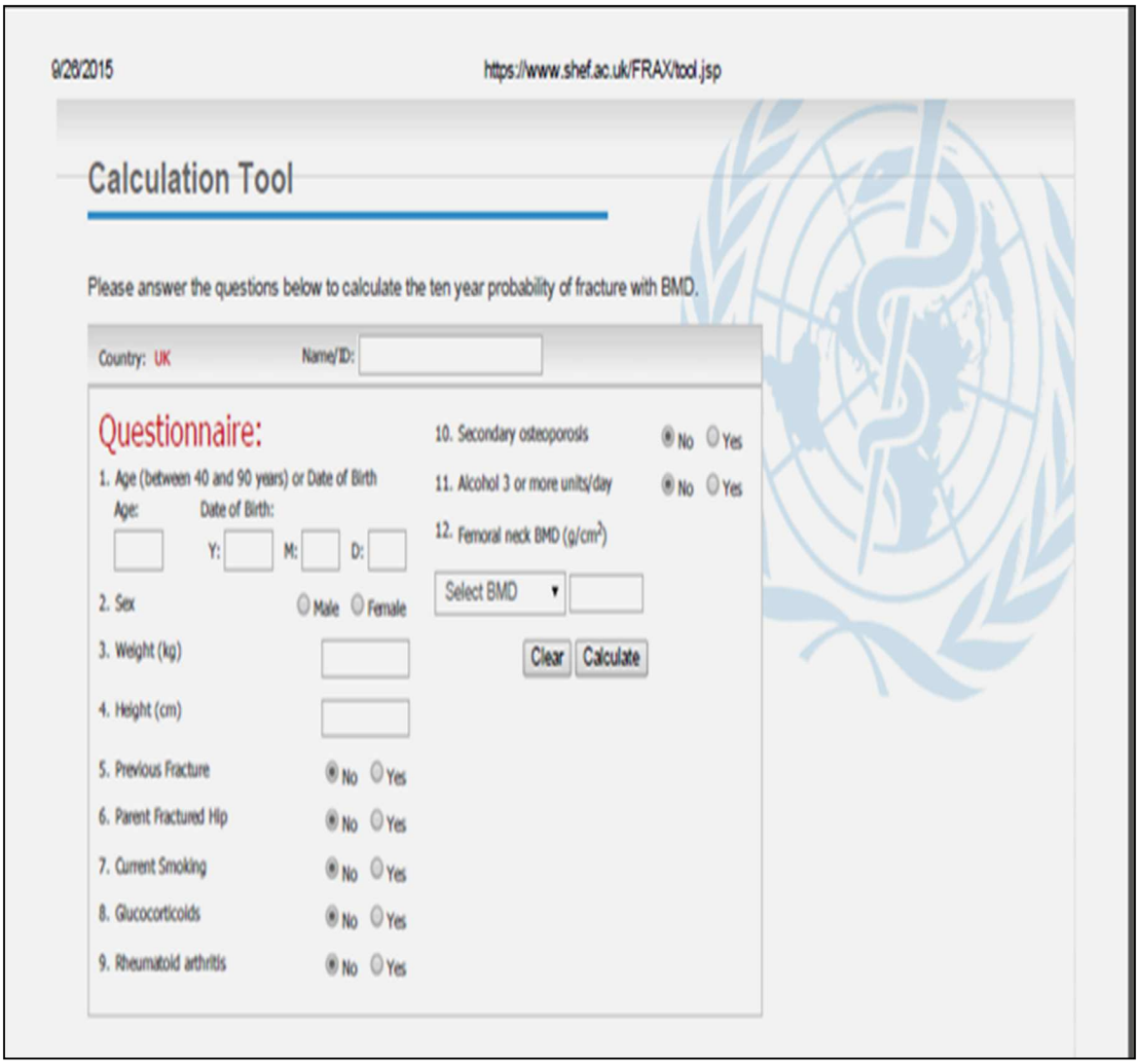
புகை பிடித்தல்

ஷாம் 1 : உணவு திட்டம் - 24 மணி நேரம் சாப்பிட்ட உணவை ஞாபகபடுத்தல்.

உணவு	நேரம்	என்ன மற்றும் எவ்வளவு?
அதிகாலை		காபி/டீ/பால்/கஞ்சி
காலை உணவு (டிபன்)		இட்லி/தோசை/சம்மாத்தி/பூரி/ உப்புமா/ சப்பாத்தி/பரோட்டா/சேமியா சட்டினி-தேங்காய்/வேர்கடலை/ தக்காளி/வெங்காயம்
நடு காலை		காபி/டீ/பால்/கஞ்சி/படிசாறு பிஸ்கெட் (சாதாரணமான/கிரிம்/உப்பு/ வெள்ளை) கிரீம்பன்/பன் பட்டர் மற்றும் ஜாம் பிரோடு பட்டர் மற்றும் ஜாம்/கேக் (கிரீம்/சாதாரணம்/ சமோச/ பப்சு(வெஜ்/முட்டை/மட்டன்/சிக்கன்)

		வடை/பஜ்சி
மத்திய உணவு		சாதம்/சம்பார்/ரசம்/காரைக்குளம்பு/ குருமா/தேங்காய் குளம்பு பட்டன் குளம்பு/சிக்கன் குளம்பு/ மீன் குளம்பு மட்டன்/சிக்கன்/மீன்/முட்டை கேரடு/பிட்குரு/காளிபிளவர்/பின்ஸ்/ வெண்டக்காய்/முருங்கைகாய்/ கத்திரிக்காய்/அவரைக்காய்/கோஸ்/ உருளைக்கிழங்கு/சேமைக்கிழங்கு பச்சைக்காய்கறி–சிறுகிரை/அரக்கிரை/ முருங்ககிரை/மனதக்காளி/அவத்திகிரை/ பொன்னாங்குனி
மாலை நேரம்		
இரவு உணவு		
படுக்கை நேரம்		பால்
நடுவில் உட்கொள்ளுதல் (சினக்ஸ்/வெரெஜ்)		பழங்கள்–ஆப்பில்/வாழைப்பழம்/திராட்சை/ ஆரேஞ்சு/முசாம்பி/சப்போட்டா/மாம்பழம்/ மாதுளம்/அன்னாச்சி/பலாபழம்

Annexure 3



9/28/2015 https://www.shef.ac.uk/FRAX/tool.jsp

Calculation Tool

Please answer the questions below to calculate the ten year probability of fracture with BMD.

Country: UK Name/ID:

Questionnaire:

1. Age (between 40 and 90 years) or Date of Birth
   Age: Date of Birth: Y: M: D:
2. Sex ○ Male ○ Female
3. Weight (kg)
4. Height (cm)
5. Previous Fracture ◉ No ○ Yes
6. Parent Fractured Hip ◉ No ○ Yes
7. Current Smoking ◉ No ○ Yes
8. Glucocorticoids ◉ No ○ Yes
9. Rheumatoid arthritis ◉ No ○ Yes
10. Secondary osteoporosis ◉ No ○ Yes
11. Alcohol 3 or more units/day ◉ No ○ Yes
12. Femoral neck BMD (g/cm^2)
    Select BMD
    Clear Calculate

Annexure 4

Information sheet

Name of the principle investigator: Dr. Reshma Raju

Name of the organization: Department of community health, Christian Medical College, Vellore

Title: A study to find out the percentage of ambulatory elderly men with osteoporosis(weak bones with increased fracture risk) and its causes in Kaniyambadi block

we are doing a study to find out the percentage of men with osteoporosis and its causes in kaniyambadi block. We are inviting you to participate in the study. Please review this form carefully and ask any questions about the study before you agree to join. You may also ask questions at any time after joining the study

Purpose:

Elderly population is at increased risk for osteoporosis and subsequent fractures. Fractures in elderly have a huge economic burden on the family and the community. Most of the data available regarding osteoporosis is from studies done in women. Since the data from men are lacking this study purposes to find the percentage of men with osteoporosis and its causes in Kaniyambadi block.

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Procedure: You are invited to participate in the study. A questionnaire will be administered to you. You will be asked to go to CMC Vellore for a Dexa scan(similar to X ray) and blood tests. Travel expenses will be taken care of as part of the study.

Side effects: No side effects are contemplated because Dexa scan uses very low dose of X ray which is one tenth the dose used in a chest X ray.

Risks and discomfort: There will not be any or discomfort to you as the procedure(Dexa scan) is non-invasive. Blood sample will be taken in CMC to check for your Serum Calcium, phosphate, albumin and creatinine values.

Benefits: Your participation is likely to help us find answers about osteoporosis in men. This information will help us to use strategies to prevent the development of osteoporosis in men and thus reduce the incidence of fractures among elderly men.

Expenses: All investigations will be done free of cost for the patient. No cash incentives will be given for taking part in the study. Travel expense (to CMC and back) will be taken care of by the study.

Confidentiality: The information that we collect from this research project will be kept confidential. Information about you that will be collected from the study will be stored in a file and will be kept locked with access only to the primary investigator.

Right to refuse or withdraw: You do not have to join in this research if you do not wish to do so. You may stop participation in the research at any time without losing any of your rights as a patient here. Your treatment at this center will not be affected in any way.

If new information becomes available: Sometimes, after a research study has started, the researchers learn new things about osteoporosis. If this happens, we will tell you about the new information. Then you can decide whether you will continue participating.

Whom to contact: If you have any questions you may ask them now or later. If you wish to ask questions later, you may contact any of the following:

Annexure 5

தகவல் தாள்

தலைமை ஆய்வாளரின் பெயர் : டாக்டர்.ரேஷ்மா ராஜு

நிர்வாகத்தின் பெயர் : சமூக சுகாதாரத்துறை, கிருத்துவ மருத்துவக் கல்லூரி, வேலூர்.

தலைப்பு :

கணியம்பாடி வட்டாரத்தில், ஆஸ்டியோ போரோசிஸ்சால் பாதிக்கப்பட்ட ஆண்களின் சதவீதம் மற்றும் அதன் காரணங்கள் கண்டறிவதற்காக இந்த ஆய்வை நடத்துகிறோம். நாங்கள் உங்களை இந்த ஆய்வில் பங்கேற்பதற்கு அழைக்கிறோம்.

இந்த ஆய்வில் சேர, சம்மதிக்கும் முன்னதாக இந்த படிவத்தினை கவனமாக படித்து அது சம்மந்தமாக ஏதேனும் கேள்விகள் இருந்தால் கேட்கலாம்.

ஆய்வில் சேர்த்த பிறகும், உங்களுக்கு ஏதேனும் கேள்விகள் இருந்தால் எந்நேரமும் தாராளமாக கேட்கலாம்.

நோக்கம் :

ஆஸ்டியோபோராஸிஸ்-க்கும், எலும்பு முறிவுக்கும் பெரியவர்கள் அதிக பாதிப்புக்கு உள்ளாகிறார்கள்.

சமுதாயத்திலும் மற்றும் குடும்பத்திலும் இந்த மாதிரியான முறிவுகள் பெரியவர்கள் மீது பொருத்த பணச் சுமையை வைக்கின்றன.

ஆஸ்டியோபோராஸிஸ் சம்மந்தமான பல தகவல்கள் பெண்களிடம் எது நடத்தப்பட்ட ஆய்வின் மூலம் கிடைக்கப்பெற்றது. இந்த தகவல் ஆண்கள் பற்றி இல்லாததால். இந்த ஆய்வு நடத்தப்படுகிறது.

செய்முறை :

நீங்கள் இந்த ஆய்வுக்கு அழைக்கப்படுகிறீர்கள். ஒரு கேள்வித்தாள் தங்களிடம் அளிக்கப்படும். நீங்கள், சி.எம்.சி. வேலூரில், டெக்சா ஸ்கேன் செய்ய அழைக்கப்படுவார்கள். (X-Ray மாதிரியான) மற்றும் இரத்த பரிசோதனை. ஆய்வின் ஒரு பகுதியாக போக்குவரத்து செலவுகள் தரப்படும்.

பக்க விளைவுகள் :

எந்த பக்க விளைவுகளும் கிடையாது. ஏன் என்றால் டெக்சா ஸ்கேன் என்பது மிகவும் குறைந்த X-Ray டோன் அவையே பயன்படுத்துகிறது. அதாவது மார்பு X-Ray-வில், பத்தில் பிற பங்கு பயன்படுத்தப்படுகிறது.

ஆபத்து மற்றும் அசௌகரியம் :

இந்த செயல்முறையால் எந்த ஒரு ஆபத்தும், அசௌகரியமும் கிடையாது. ஏனெனில் இந்த செய் முறையால் எந்த ஒரு கருவியும் உடலுக்குள் செலுத்தப்படமாட்டாது.

கால்சியம், பாஸ்பேட், ஆல்புமின் மற்றும் கிரியாடனின் மதிப்பீடுகளை அறிய சி.எம்.சி.யில் இரத்தம் எடுக்கப்படும்.

பயன்கள் :

ஆண்களின் ஆஸ்டியோபோராஸிஸ் சம்மந்தப்பட்ட விடைகளை கண்டு அறிவதற்கு தங்களின் பங்களிப்பு உதவிகரமாக இருக்கும்.

ஆண்களில் ஆஸ்டியோபோராஸிஸ் முன்னேற்றம் அடையாமல் தடுப்பதற்கான யுக்திகளை வகுக்க இந்த தகவல் உதவியாக இருக்கும். மேலும் பெரியவர்களில் எலும்பு சம்மந்தமான முறிவுகள் குறைக்க உதவும்.

செலவுகள் :

எல்லா பரிசோதனைகளும் இலவசமாக செய்து தரப்படும். இந்த ஆய்வில் பங்கேற்பதற்கு எந்த ஒரு சந்மானமும் தரப்படமாட்டாது. போக்குவரத்து செலவுகளை ஆய்வே பொறுப்பு ஏற்கும்.

இரகசிய தன்மை :

இந்த ஆய்வின் மூலம் சேகரிக்கப்படும் அனைத்து தகவல்களும் இரகியமாக பாதுகாக்கப்படும்.

சேகரிக்கப்பட்ட உங்களின் தகவல்கள் பத்திரமாக ஒரு கோப்பில் பூட்டி வைக்கப்படும். அதை தலைமை ஆய்வாளர் எடுக்க மட்டுமே அனுமதி உண்டு.

மறுக்கும் உரிமை (அ) பின்வாங்குவது :

உங்களுக்கு விருப்பம் இல்லை என்றால் இந்த ஆய்வில் சேர வேண்டாம்.

புதிய செய்திகள் இருக்குமானால் :

இந்த ஆராய்ச்சியை மேற்கொண்ட ஆராய்ச்சியாளரால் இந்த நோய் (ஆஸ்டியோ போராஸிஸ்) பற்றிய புதிய செய்தி (அ) தகவல் கிடைத்தால் ஆராய்ச்சியாளர் அதைப்பற்றி உங்களிடம் சொல்வார்கள். இதற்கு பின் நீங்கள உங்கள் விருப்பம் இருந்தால் இதில் கலந்து கொள்ளலாம்.

தொடர்புகொள்ள வேண்டிய நபர் :

உங்களுக்கு ஏதேனும் கேள்வி இருந்தால், நீங்கள் இப்போது (அ) எப்போதும் இந்த ஆராய்ச்சியாளரிடம் கேட்கலாம்.

Annexure 6

Informed Consent form to participate in a research study

Study Title: Prevalence and risk factors for osteoporosis in ambulatory elderly men in a rural area of South India: a cross sectional study

Study Number: _____Subject's Initials:_____

Subject'sName: _____

Date of Birth / Age: _____

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the study, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable

Date: _____/_____/_____

Signatory's Name: _____ Signature:

Or

Representative: _____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date: _____/_____/_____

Study Investigator's Name: _____

Signature or thumb impression of the Witness: _____

Date: _____/_____/_____ Name & Address of the Witness: _____

Annexure 7

இந்த ஆய்வில் பங்கு பெறுவோருக்கான ஒப்புதல் படிவம்

தலைப்பு :

கணியம்பாடி வட்டாரத்தில், ஆஸ்டியோபோராஸிஸ்சால் பாதிக்கப்பட்ட ஆண்களின் சதவீதம் மற்றும் அதன் காரணங்களை கண்டறிவதற்காக இந்த ஆய்வை நடத்துகிறோம். நாங்கள் உங்களை இந்த ஆய்வில் பங்கேற்பதற்கு அழைக்கிறோம்.

படிவ எண் :

ஒப்புதல்காரரின் பெயர் :

பிறந்த தேதி / வயது :

1. நான் தகவல் தாளில் உள்ள தகவல்களை படித்து உறுதியாக தெரிந்து கொண்டேன், மற்றும் எனக்கு அதில் உள்ள இந்த சந்தேகங்களை கேட்டு தெரிந்து கொள்ள சந்தர்ப்பமும் கிடைத்தது.

2. என்னுடைய பங்களிப்பு இந்த ஆய்வில் சுயமானது, உனக்கும் எப்போது இந்த ஆய்வில் இருந்து விலக வேண்டுமோ அப்போது எந்த ஒரு காரணமும் இன்றி, மருத்து வசதி மற்றும் என்னுடைய சட்ட உரிமை எதுவும் பாதிக்கப்படாது என்பதை புரிந்து கொண்டேன்.

3. இந்த ஆய்வை நடத்துபவராலோ அல்லது நடத்தும் நிறுவனத்தினாலோ என்னுடைய ஆரோக்கிய படிவத்தை என்னுடைய அனுமதியின்றி இந்த அய்விற்காக பார்க்கலாம், அவர்களுடைய ஆய்வில் இருந்து நான் பாதியில் வெளியேறினாலும் அதைப்பற்றி செய்திகளுக்கு என்னிடம் பகிர்ந்து கொள்ளலாம். நான் இதை ஒத்துக்கொள்கிறேன். என்னுடைய அடையான்

எந்த ஒரு மூன்றாம் நபரிடமும் பகிர்ந்து கொள்ளப்படாது என்பதை புரிந்து கொள்கிறேன்.

4. இந்த அறிவியல் ஆராய்ச்சிக்காக கேட்கப்படும் அனைத்து கேள்விகளையும், தகவல்களையும் நிராகரிக்கமாட்டேன்.

5. நான் இந்த ஆய்வில் பங்கெடுக்க விரும்புகிறேன்.

கையெழுத்து (அல்லது) இடது பெருவிரல் முத்திரை)

ஆய்வின் மூலமாக சட்டப்பூர்வமாக ஒப்புத

தேதி : கையெழுத்து

ஆய்வாளரின் பெயர்

(அல்லது)

சுற்றாதாரரின் கையொப்பம் தேதி :

ஆய்வாளரின் பெயர் :

ஆய்வாளரின் கையெழுத்து : தேதி

சாட்சி கையெழுத்து தேதி :

சாட்சியின் பெயர் மற்றும் முகவரி :

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA.

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho
Chairperson, Research Committee & Principal

Dr. Nihal Thomas,
MD., MNAMS., DNB (Endo), FRACP (Endo), FRCP (Edin), FRCP (Glasg)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

February 11, 2015

Dr. Reshma Raju
PG Registrar
Department of Community Health
Christian Medical College, Vellore 632 002

Sub: **Fluid Research Grant Project:**
Prevalence and risk factors for osteoporosis in ambulatory elderly men in a rural area of South India: a cross sectional study.
Dr. Reshma Raju, Dr. Vinod Joseph Abraham, Community Health, Dr. Thomas Paul, Endocrinology, Dr. Nihal Thomas, Dr. Nitin Kapoor, Endocrinology, CMC, Vellore.

Ref: IRB Min No: 9210 [OBSERVE] dated 08.12.2014

Dear Dr. Reshma Raju,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Alfred Job Daniel
Chairperson, Research Committee & Principal
Institutional Review Board
Christian Medical College, Vellore.

Dr. Alfred T. Daniel
MBBS, D.Ortho, MS (Ortho), DNB (Ortho)
Principal
Christian Medical College
Vellore - 632 002.

Cc: Dr. Vinod Joseph Abraham, Community Health, CMC, Vellore.

...cs Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
. 0416 - 2284294, 2284202 Fax : 0416 - 2262788, 2284481 E-mail : research@cmcvellore.ac.in

OFFICE OF RESEARCH
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Ref: IRB Min No: 9210 [OBSERVE] dated 08.12.2014

Dear Dr. Reshma Raju,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Prevalence and risk factors for osteoporosis in ambulatory elderly men in a rural area of South India: a cross sectional study." on December 08th2014.

The Committees reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. Reshma Raju, Vinod Joseph Abraham, Thomas Paul, Nihal Thomas, NitinKapoor
3. Informed Consent form (English & Tamil)
4. Information Sheet (English & Tamil)
5. Questionnaire
6. No of documents 1-5

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on December 08th 2014 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Other Affiliations
Dr. Ranjith K Moorthy	MBBS M Ch	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Dr. Niranjan Thomas	DCH, MD, DNB (Paediatrics)	Professor, Neonatology, CMC	Internal, Clinician
Dr. Jacob John	MBBS, MD	Associate Professor, Community health	Internal, Clinician
Dr. Rajesh Kannangai	MD, Ph D.	Professor & In-charge Retrovirus Laboratory (NRL under NACO), Department of Clinical Virology, CMC, Vellore	Internal, Clinician
Dr. Anup Ramachandran	Ph. D	The Wellcome Trust Research Laboratory Gastrointestinal Sciences, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Simon Pavamani	MBBS, MD,	Professor, Radiotherapy, CMC, Vellore	Internal, Clinician
Dr. Visalakshi. J	MPH, PhD	Lecturer, Dept of Biostatistics, CMC, Vellore	Internal, Statistician

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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Dr. T. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA(Theology), Dr. Min(Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, Vellore	External, Social Scientist
Mrs. Pattabiraman	B. Sc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. Denise H. Fleming	B. Sc (Hons), PhD	Honorary Professor, Clinical Pharmacology, CMC, Vellore	Internal, Scientist & Pharmacologist
Dr. Anuradha Rose	MBBS, MD	Assistant Professor, Community Health, CMC, Vellore	Internal, Clinician
Mrs. Sheela Durai	MSc Nursing	Addl. Deputy Nursing Superintendent, Professor of Nursing in Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Mr. C. Sampath	BSc, BL	Legal Expert, Vellore	External, Legal Expert
Rev. Joseph Devaraj	B. Sc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002.
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Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

Dr. Nihal Thomas,	MD, MNAMS, DNB(Endo), FRACP(Endo) FRCP(Edin) FRCP (Glasg)	Professor & Head, Endocrinology. Additional Vice Principal (Research), Deputy Chairperson, IRB, Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician

We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any **adverse events** occurring in the course of the project, any **amendments in the protocol and the patient information / informed consent**. On completion of the study you are expected to submit a copy of the **final report**. Respective forms can be downloaded from the following link: http://172.16.11.136/Research/IRB_Polices.html in the CMC Intranet and in the CMC website link address: http://www.cmch-vellore.edu/static/research/Index.html.

Fluid Grant Allocation:

A sum of 50,000/- INR (Rupees Fifty Thousand only) will be granted for 6 months.

Yours sincerely

Dr. Alfred Job Daniel
Chairperson, Research Committee & Principal
Institutional Review Board
Christian Medical College, Vellore.

Dr. Alfred J. Daniel
MBBS, D Ortho, MS (Ortho), DNB (Ortho)
Principal
Christian Medical College
Vellore - 632 002.

Cc: Dr. Vinod Joseph Abraham, Community Health, CMC, Vellore.

IRB Min No: 9210 [OBSERVE] dated 08.12.2014 4 of 6

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD
CHRISTIANMEDICALCOLLEGE,
BAGAYAM, VELLORE 632002, TAMIL NADU, INDIA

Ref: FG/9210/12/2014

February 14, 2015

Mr. Robby Pria Sundersingh
The Treasurer
Christian Medical College,
Vellore.

Dear Mr. Robby Pria Sundersingh,

Sub: **Fluid Research Grant Project:**
Prevalence and risk factors for osteoporosis in ambulatory elderly men in a rural area of South India: a cross sectional study.
Dr. Reshma Raju, Dr. Vinod Joseph Abraham, Community Health, Dr. Thomas Paul, Endocrinology, Dr. Nihal Thomas, Dr. NitinKapoor, Endocrinology, CMC, Vellore.

Ref: IRB Min. No. 9210 dated 08.12.2014

The Institutional Review Board at its meeting held on December 08th 2014 vide IRB Min. No. **9210** accepted the project for *50,000/- INR (Rupees Fifty Thousand only) will be granted for 6 months. If overspent the excess should be debited form the respective departmental or Special funds.* Kindly arrange to transfer the sanctioned amount to a separate account to be operated by Dr. Reshma Raju (Reshma_raju21@yahoo.com) and Dr. Vinod Joseph Abraham (vinodabraham@cmcvellore.ac.in)

Yours sincerely,

Dr. Nihal Thomas
Secretary (Ethics Committee)
Institutional Review Board

Dr. NIHAL THOMAS
MD, MNAMS, DNB(Endo), FRCP(Edin), FRCP(Glasg)
SECRETARY (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

OFFICE OF THE TREASURER
26 FEB 2015
23716
VELLORE - 632 004

CC: Dr. Reshma Raju, Community Health, CMC, Vellore
Dr. Vinod Joseph Abraham, Community Health, CMC, Vellore.
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